



Homeland Security

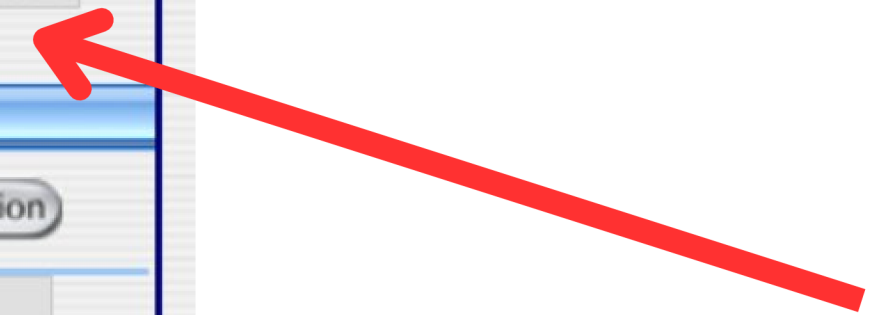
In response to the 2001 anthrax attacks, the President and Congress established the BioWatch Program (BioWatch) in 2003.¹ The program embarked on an aggressive effort to deploy a nationwide system to surveil for aerosolized exposure caused by the intentional release of biological agents. This system was initiated in 30 of the most populous cities within the United States. After the creation of DHS, BioWatch was initially established under the Science and Technology Directorate, and in 2007 was transferred to DHS' Office of Health Affairs. Then, in 2018, BioWatch transferred to DHS' Countering Weapons of Mass Destruction (CWMD) office with a budget averaging \$76 million per fiscal year from 2018 to 2020.²

Dates		Amounts	
Date Signed (mm/dd/yyyy) :	10/19/2021		
Period of Performance Start Date (mm/dd/yyyy) :	09/30/2016	Action Obligation:	Current: -\$31,658.43 Total: \$974,297.67
Completion Date (mm/dd/yyyy) :	09/29/2019	Base And Exercised Options Value:	-\$31,658.43 \$974,297.67
Est. Ultimate Completion Date (mm/dd/yyyy) :	10/14/2022	Base and All Options Value (Total Contract Value):	-\$31,658.43 \$2,136,843.99
Solicitation Date (mm/dd/yyyy) :		Fee Paid for Use of IDV:	\$0.00

Purchaser Information			
Contracting Office Agency ID:	7001	Contracting Office Agency Name:	OFFICE OF PROCUREMENT OPERATIONS
Contracting Office ID:	70RWMD	Contracting Office Name:	CWMD ACQ DIV
Funding Agency ID:	7062	Funding Agency Name:	COUNTERING WEAPONS OF MASS DESTRU
Funding Office ID:	70DWM1	Funding Office Name:	ASST SCTY COUNTERING WPNS OF MASS C
Foreign Funding:	Not Applicable		

Entity Information			
FAR 4.1102 Exception: <input type="text"/> Remove Exception			
Unique Entity ID:	TKS7NBB4JDN6	Street:	460 W 34TH ST 17TH FL
Legal Business Name:	ECOHEALTH ALLIANCE INC.	Street2:	
DBAN:		City:	NEW YORK
CAGE Code:	3MMU3	State:	NY Zip: 100012320
		Country:	UNITED STATES
		Phone:	(212) 380-4479
		Fax No:	(212) 380-4465
		Congressional District:	NEW YORK 12

Business Category		Show Details	
Organization Type:	CORPORATE TAX EXEMI	Business Types	
State of Incorporation:	MA	Relationship With Federal Government	
Country of Incorporation:	USA	Organization Factors	



**Funder: DHS, Countering
Weapons of Mass
Destruction**

What specific research projects has EcoHealth Alliance conducted with the funding from the Department of Countering Weapons of Mass Destruction

The search results do not provide specific information on the research projects that EcoHealth Alliance conducted with the funding from the Department of Countering Weapons of Mass Destruction. However, according to a news article, the Defense Threat Reduction Agency (DTRA) began awarding funding to EcoHealth Alliance for a work program labeled "Scientific Research – Combating Weapons of Mass Destruction" beginning in fiscal year 2014 ¹. The DTRA describes its mission as "to protect the United States and its allies by enabling the DoD and international partners to detect, deter, and defeat WMD and threat networks" ¹. The funding from the DTRA was part of the Department of Defense's efforts to protect the United States and its allies by enabling the DoD and international partners to detect, deter, and defeat WMD and threat networks ¹.

what is the role of industry/academia collaboration in CWMD research and prototype work

The Countering Weapons of Mass Destruction (CWMD) Office executes research and prototype work through project teams from a broad-based industry/academia collaboration ¹ ² ³. The CWMD Consortium is an enterprise through which the Department of Defense CWMD/CBRN community, industry, and academia work collaboratively to develop prototype solutions ¹. CWMD, in collaboration with interagency and private-sector partners, identifies technological trends and advancements relevant to chemical, biological, radiological, and nuclear threats ⁴. The Medical CBRN Defense Consortium (MCDC) also executes research and prototype work through project teams from a broad-based industry/academia collaboration ³. The role of industry/academia collaboration in CWMD research and prototype work is to bring together experts from different fields to develop innovative solutions to detect, deter, and defend against chemical, biological, radiological, and nuclear threats ⁵. By working collaboratively,

Global Argus



4 February, 2008

UNCLASSIFIED

Page 1

Project ARGUS Global

UNCLASSIFIED

Intelligence Technology Innovation Center
ITIC

Mission

ARGUS provides a global biological event detection and tracking capability that yields actionable early warning alerts

UNCLASSIFIED

Page 2

History

ITI

- R&D began in summer 2004.
- Utilizes COTS and GOTS. Argus has never been an IT research program.
- Began experimental testing in December 2004 with support for Tsunami relief efforts.
- Coverage concentrated in Pacific Rim.
- In August 2005, a plan was requested to move Argus into global operation to track Avian Influenza.

History *(continued)*

ITI

- During 2005 and 2006, development work continued on IT platforms, software, and analytical taxonomies.
- Funded in mid-June 2006 to field an operational system.
- Began operations in late July, 2006.
- Within one month, achieved global reach with coverage of 195 of 196 US-recognized countries.
- Achieved initial operating capability in late November, 2006.
- Full operational capability was attained in July, 2007, and the final major system was delivered in January 2008.

Approach

Intelligence Technology Innovation Center
ITIC

- Assemble social disruption key word queries from SME-derived Indicators and Warnings (I&Ws).
- Acquire collection and modeling capabilities to capture and analyze articles from the World Wide Web.
- Develop and implement an automated cueing and alerting capability.

What We Don't Do

Intelligence Technology Innovation Center
ITIC

- Ground truthing
- Pathogen diagnostics

Argus is a cueing and alerting capability that complements the long established public health and attribution investigation approaches used by other organizations.

Summary

- Argus is changing the expectations for bioevent detection.
- The system has been reduced to practice on a global scale. Actively tracking avian influenza and 130 other infectious diseases.
- Reports sent to over 300 accounts (many with multiple users) in approximately 200 organizations.
- The Argus process can have much broader application in even tracking of other issues.

Summary (continued)

- The private sector has been engaged.
- Exploring other real time data sources.
- Completed and transferred the Argus Global Information System (AGIS). AGIS is more robust and stable than its predecessor. Third generation platform (Apollo) was delivered in January, 2008.
- Continuing OFA funding of R&D component to complement and support Argus.
- Exploring real time cueing of U.S. based hospital infrastructure.

Ellen P. Carlin, D.V.M.

Assistant Research Professor

Areas of Expertise

- Zoonoses, with a focus on viral and parasitic pathogens
- Emerging infectious disease epidemiology and policy
- U.S. biodefense policy
- Global health security policy

Professional Memberships

- American Veterinary Medical Association
- License to practice

Dr. Ellen Carlin is Assistant Research Professor of Science and Security with a faculty appointment in Microbiology and Immunology. Her research focuses on emerging infections and adequate surveillance of zoonotic transmission dynamics of zoonotic pathogens in people, animals, and the environment. She has led infectious disease projects in Liberia and studies the adequacy and impact of surveillance for bioterror risks. At Georgetown, she is the Director of the Disease Master of Science program.

Ellen previously served as Senior Health and Policy Specialist at EcoHealth Alliance, where she is now Research Fellow. She has for years provided consulting services in writing, editing, and provision of technical expertise, including as founding staff, Co-Director, and Senior Advisor to the Bipartisan Commission on Biodefense. In 2013, she completed a fellowship with the U.S. Food and Drug Administration Center for Veterinary Medicine on data analysis and other aspects of antimicrobial resistance. Prior to that, she was Senior Professional Staff with the U.S. House of Representatives Committee on Homeland Security (Peter T. King, NY), where for more than five years, she handled medical preparedness, biodefense, and science and technology policy. That position began as an American Veterinary Medical Association/American Association for the Advancement of Science fellowship.

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Ellen works with her alma mater as Courtesy Lecturer at the Cornell College of Veterinary Medicine, where she teaches a class on the role of the federal government in animal health. She has worked or volunteered since 2007 as a small animal clinical veterinarian and continues to participate in low income and vaccine clinics, serving her interests in animal health and welfare, public health, and parasitology. She received a Bachelor of Science in biology from the College of Mount Saint Vincent and a doctorate in veterinary medicine from the Cornell College of Veterinary Medicine.

[GU](https://www.georgetown.edu) <https://www.georgetown.edu> › news › bill-and-hillary-clinton-u-s-and-foreign-policymakers...

Bill and Hillary Clinton, U.S. and Foreign ... - Georgetown University

Sep 30, 2022 · Bill Clinton first met Albright when she was working on the Michael Dukakis presidential campaign. The Clintons Remember Albright. The day's final conversation between Bill and Hillary Clinton was moderated by Ambassador Melanne Verveer (I'66, G'69), executive director of the Georgetown Institute for Women, Peace and Security, who knew the former president during their time as students ...



Division of Integrated BioDefense

ISIS Center, Georgetown University Medical Center

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Project Argus

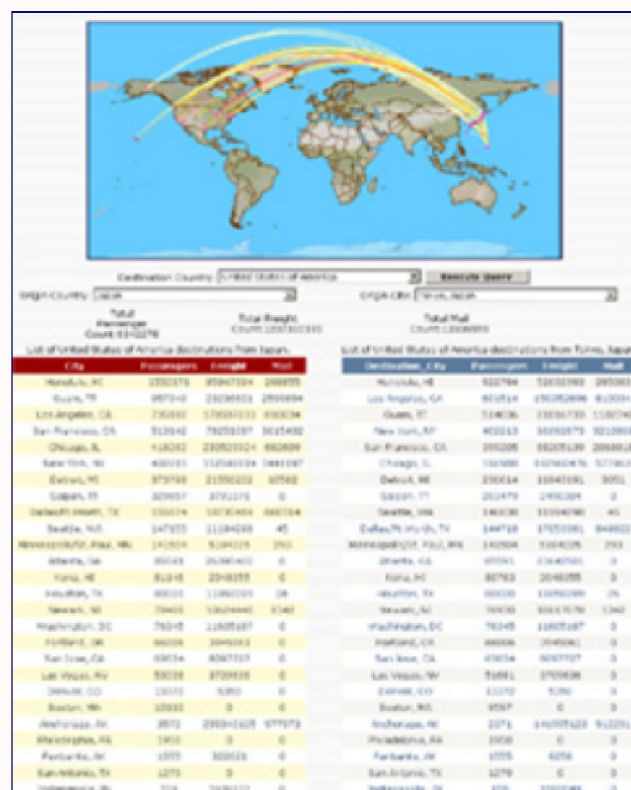


Fig. 1: Air-Transportation Query Page

The frequency of biological events with a potential impact on homeland security is increasing, and current disease surveillance systems in the United States (U.S.) have been inefficient in their capacity to detect these events in a timely fashion. The clear and present danger to the United States spans infectious diseases of humans, animals, and plants.

Indications and Warnings (I&Ws) alert U.S. responders of an imminent bioevent weeks to months in advance. I&Ws are markers occurring globally, outside of U.S. borders, before an outbreak can affect U.S. interests, forces, citizens, or territory, thus allowing the U.S. time to respond. In effect, I&Ws can prime the national response infrastructure by alerting agencies of an evolving threat that could ultimately be catastrophic. Retrospective analyses of major bioevents have demonstrated the presence of multiple I&Ws were present in multiple data sources weeks to months in advance, which were not recognized and utilized properly by the national response community.

For the U.S. to meet present and future biothreats that span agricultural, animal, and human considerations, an integrative strategy for information discovery,

exploitation, and effective proactive use by the response community is critical. I&Ws provide a key component for integration within the U.S. biosurveillance portfolio, enabling earlier warning potential. Project Argus is the first attempt to integrate I&Ws in effort to detect catastrophic bioevents on an international scale. The Argus system serves as a primer for U.S. countermeasure response plans in the context of a potentially catastrophic bioevent. Project ARGUS is jointly funded by the US Army Medical Research and Materiel Command Telemedicine and Advanced Technology Research Center (USAMRMC-TATRC) and the Department of Homeland Security.

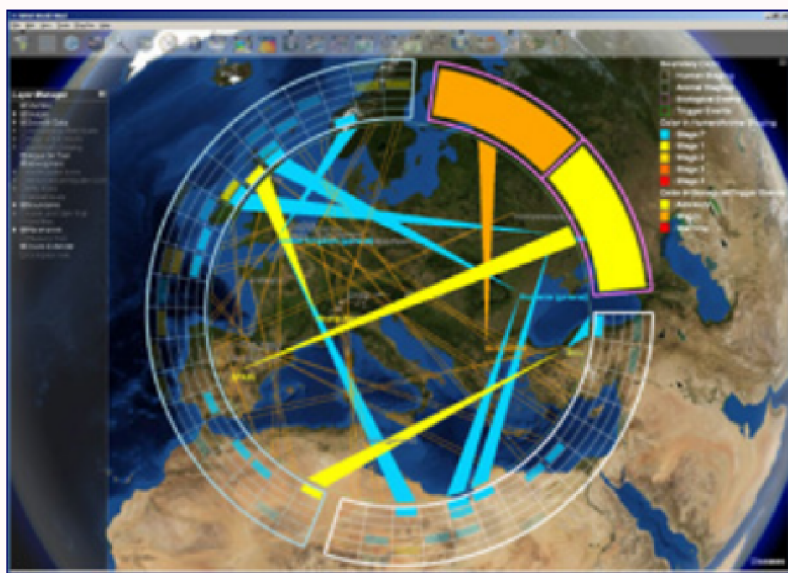


Fig. 2: Situation Awareness Tool (High-lighting Europe).

Contact Information


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Division Director: James M. Wilson, MD
e-mail: wilson@isis.georgetown.edu



Organizations



Search by keyword, skill, or interest

 Chesapeake

**Imaging Science and
Information Systems (ISIS)
Center - Georgetown
University**

Joined in March 2007

Do you work for Imaging Science and
Information Systems (ISIS) Center -
Georgetown University? [Become an
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About Us

The Imaging Science and Information Systems (ISIS) Center, under the
Department of Radiology at the Georgetown University Medical Center, is a
medical research organization with over 60 full-time faculty and staff
specializing in the use...

[Read more about this organization](#) 



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College Says It Owns Global Pandemic Warning System

NEWS DESK / August 3, 2009



WASHINGTON (CN) - Georgetown College sued two former employees who refuse to give up their patent rights to inventions for "Project Argus," a federally funded project for "technology capable of supporting a worldwide biosurveillance system" that can detect outbreaks of disease before they become pandemics.

Georgetown says six joint inventors from Georgetown worked on Project Argus inventions, but defendants Dr. James Wilson and Mark Polyak refused to assign their rights to the university when they resigned in spring 2008.

Georgetown's Imaging Science and Information Center collaborated with the nonprofit Mitre Corp. to create Argus, which was awarded the National Intelligence Medallion in 2008, the college said.

Georgetown says six joint inventors from Georgetown worked on Project Argus inventions, but defendants Dr. James Wilson and Mark Polyak refused to assign their rights to the university when they resigned in spring 2008.

Georgetown's Imaging Science and Information Center collaborated with the nonprofit Mitre Corp. to create Argus, which was awarded the National Intelligence Medallion in 2008, the college said.

Wilson spoke about the project at a 2005 Georgetown conference on infectious diseases, hailing Argus as the first attempt to produce intelligence on foreign bioevents so that the United States can avert a catastrophic epidemic.

Named after the 100-eyed sentinel from Greek mythology, Argus technologies study early indications and warnings of infectious disease to give responders notice before an epidemic peaks and is harder to contain.

At the 2005 Georgetown conference, another speaker introduced a doctrine of biosurveillance that would govern the project's access to "sensitive material" but not classified data in monitoring outbreaks.

"Because no single public law governs such heterogeneous data, investigators have analyzed numerous sources, including federal laws, Executive Orders

"Because no single public law governs such heterogeneous data, investigators have analyzed numerous sources, including federal laws, Executive Orders, international directives, agency policies and procedures, Congressional testimony, and reports by governmental and nongovernmental bodies [to create] the Biosurveillance Doctrine, a document that thoroughly explains conditions under which Project Argus will acquire, analyze, protect, and use data," Georgetown said in a statement about the conference.

After three years of development, Argus became operational in June 2007 and has already detected outbreaks before they became pandemics, according to a 2008 article in Security Management Magazine.

Argus followed the appearance of Ebola in the Democratic Republic of the Congo, the spread of the H5N1 avian flu from China into Russia and a minor hoof-and-mouth outbreak in the United Kingdom.

Security Risk Solutions, a South Carolina-based consulting firm, supports the project in a statement on its Web site.

"Instead of waiting for reports from local doctors and hospitals, Argus uses software that treats the Earth's communications almost like a giant EKG,

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"Instead of waiting for reports from local doctors and hospitals, Argus uses software that treats the Earth's communications almost like a giant EKG, looking for certain kinds of spikes in global information networks," Security Risk says. "Search programs zero in on key words on the Internet and in news media that might indicate an epidemic, such as heavy rates of absenteeism, runs on pharmaceutical drugs, and migration away from villages and towns."

Georgetown says its employment policy requires the defendants to surrender their patent rights and it seeks an order directing them to do so. Georgetown is represented by Thomas Hentoff with Williams & Connolly.

Categories: [UNCATEGORIZED](#)

DESIGNING ETHICAL PRACTICE IN BIOSURVEILLANCE

The Project Argus Doctrine

JEFF COLLMANN^{1,*} and ADAM ROBINSON²

CHAPTER OVERVIEW

Biosurveillance entails the collection and analysis of information needed to provide early warning of outbreaks of infectious disease, both naturally occurring and intentionally introduced. Data derived from repositories containing various types of sensitive information may be required for this purpose, including individually identifiable, copyrighted, and proprietary information. The Project Argus Biosurveillance Doctrine was developed to ensure that ethical and legal principles guide the collection and handling of such information. Project Argus does not, however, use individually identifiable information or any material derived from individually identifiable information for any phase of the project. Further, Project Argus is not used for purposes of law enforcement, counterterrorism, or public health surveillance. This chapter details why and how the doctrine was developed and summarizes its guiding principles and key elements.

Keywords: Biosurveillance; Sensitive information; Information protection; Privacy

^{1*} O'Neill Institute for National and Global Health Law, Disease Prevention and Health Outcomes, School of Nursing and Health Studies, Georgetown University Medical Center, Box 571107, 3700 Reservoir Rd, NW, Washington, DC 20057-1107, USA, collmanj@georgetown.edu

² The MITRE Corporation, 7515 Colshire Drive, McLean, VA 22102, USA

2. BACKGROUND

Project Argus developed the technical and doctrinal requirements for an integrated, multisource information system designed to perform global bio-

2. *Designing Ethical Practice in Biosurveillance*

25

surveillance for epidemics; biological accidents; and bioattacks on humans, animals, and plants [1].

The ethical issues surrounding the development and maintenance of such a system have been a key consideration from the outset of Project Argus. No single public law or set of regulations governs the handling and protection of the broad range of sources, types, security classifications, and potential uses of the information to be collected and analyzed. Therefore, the Project Argus doctrine team was formed to develop the necessary guidance. The resulting biosurveillance doctrine sets forth explicit principles, management structures, policies, procedures, and technical design requirements intended to ensure the ethical handling and use of sensitive information by project participants. In this respect, a strong moral, organizational, and technical divide exists between Project Argus and initiatives that have drawn the censure of Congress, the media, and the American public for their failure to ensure such protections. After describing the methods used to develop the doctrine, we provide a high-level view of its guiding principles and key elements.

It should be noted that the version of the doctrine presented here applies only to the acquisition, archiving, analysis, and presentation of biosurveillance information in Project Argus. The doctrine team analyzed a broad set of sensitive information, including individually identifiable, copyrighted and public information. We include our analysis of and approach for handling this broad set of sensitive information for the sake of completeness and as a guide to others. Project Argus does not use any individually identifiable information in any phase of the project.

[House Hearing, 110 Congress]
[From the U.S. Government Printing Office]

ONE YEAR LATER--IMPLEMENTING THE BIOSURVEILLANCE REQUIREMENTS OF THE 9/
11 ACT

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HEARING

before the

SUBCOMMITTEE ON EMERGING
THREATS, CYBERSECURITY,
AND SCIENCE AND TECHNOLOGY

of the

COMMITTEE ON HOMELAND SECURITY
HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

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<GRAPHIC OMITTED> See the end of the file for all omitted graphics

ONE YEAR LATER, IMPLEMENTING THE BIOSURVEILLANCE REQUIREMENTS OF THE
9/11 ACT

Wednesday, July 16, 2008

U.S. House of Representatives,
Committee on Homeland Security,
Subcommittee on Emerging Threats, Cybersecurity, and
Science and Technology,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:19 p.m., in
Room 311, Cannon House Office Building, Hon. James R. Langevin
[Chairman of the subcommittee], presiding.

Present: Representatives Langevin, Christensen, Pascrell,
and McCaul.

Mr. Langevin. The subcommittee will come to order.

The subcommittee is meeting today to receive testimony on
the current state and future course of the National
Biosurveillance Integration Center, NBIC, and Project BioWatch.

Before I begin my opening statement, I wanted to mention to
the witnesses that there is a committee rule that testimony is
supposed to be in 48 hours in advance. We got the DHS testimony
this morning. We can't do business like that, and I will
caution you about ever doing it again. I don't want to have the
testimony received by this subcommittee that late ever again.
It is unacceptable. We just can't do business that way.

With that, good afternoon. I would like to thank my
colleagues for their participation, and I welcome our witnesses
here today.

As this committee is well aware, the threat of biological
attack is real and potentially catastrophic. As the Chairman of
the subcommittee, I have made it a priority to address the most
glaring vulnerabilities facing our Nation, and this is
certainly one of them. Of equal or greater concern, of course,
is the possibility that a naturally occurring disease outbreak
could grow to epidemic proportions. We have held numerous
hearings on how better to protect against biological attack,
and today we are continuing those efforts.

Today, our focus will be on determining whether the
biosurveillance requirements included in the Implementing
Recommendations of the 9/11 Act of 2007, which became law on
August 3, 2007, have been properly implemented. The 9/11 Act
included two key sections regarding our Nation's
biosurveillance capabilities. Section 1101 authorized the
National Biosurveillance Integration Center, or NBIC, and



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Biological Threat Detection and Response Challenges Remain for BioWatch (REDACTED)

UNITED STATES. DEPARTMENT OF HOMELAND SECURITY. OFFICE OF INSPECTOR GENERAL

From the Highlights: "The BioWatch Program (BioWatch) is intended to detect biological agents and provide early warning in the event of a biological attack. We conducted this audit to determine to what extent BioWatch's information sharing ensures nationwide readiness in response to biological terrorism threats."

Details

URL	https://www.hsdl.org/c/view?docid=850663
Publisher	United States. Department of Homeland Security. Office of Inspector General
Report Number	Department of Homeland Security, Office of Inspector General, Report No. OIG-21-22
Date	2 Mar, 2021
Copyright	Public Domain
Retrieved From	Department of Homeland Security Office of Inspector General: www.oig.dhs.gov/

How much money went into the Department of Homeland Security's BioWatch program?

📄 PERPLEXITY

According to the search results, the funding for the BioWatch program, which is part of the Department of Homeland Security, has varied over the years. Here is a breakdown of the funding information found:

- FY2003: The DHS reportedly spent approximately \$40 million on the BioWatch program ¹.
- 2007: The original 31 city program cost \$60 million ².
- FY2013-FY2014: Proposed funding for programs in the DHS Office of Health Affairs was reduced to \$101.3 million, a 24% reduction from estimated FY2013 funding levels ³.
- FY2022: The DHS budget provides \$52.2B in net discretionary funding, with an additional \$18.8B for the Disaster Relief Fund ⁴.
- Current funding: There is no information in the search results about the current funding for the BioWatch program.

Therefore, it is unclear how much money went into the Department of Homeland Security's BioWatch program overall, as the funding has varied over the years and there is no information about the current funding.

1



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





dhs

What is the ISIS center at Georgetown University?

↳ PERPLEXITY

The ISIS Center at Georgetown University is not related to the terrorist organization ISIS. Instead, it stands for Imaging Science and Information Systems Center. It is a research center under the Department of Radiology at the Georgetown University Medical Center ¹. The center focuses on the development of advanced medical imaging technologies and information systems ². It was established in the 1980s and 1990s and was led by Seong K. Mun ³. The center is not to be confused with the Center for Security Studies, which is another academic research center in the School of Foreign Service that offers a master's degree program ⁴.

- 1  idealism
- 2  georgetown
- 3  georgetown
- 4  georgetown



what is the focus of the ISIS center at Georgetown University

↳ PERPLEXITY

The ISIS Center at Georgetown University is the Imaging Science and Information Systems Center, which is a research center under the Department of Radiology at the Georgetown University Medical Center ¹. The center focuses on the development of advanced medical imaging technologies and information systems ¹. The center was established in the 1980s and 1990s and was led by Seong K. Mun ². The center is not related to the terrorist organization ISIS ¹.

- 1  georgetown
- 2  idealism

What connection is there between Georgetown University's ISIS Center and project argus?

📄 PERPLEXITY

There is no clear connection between Georgetown University's ISIS Center and Project Argus. However, there is a mention of Georgetown University's Argus Project in a 2007 report on global health challenges ¹. It is unclear what this project refers to, but it is not related to the ISIS Center. The ISIS Center is a research center under the Department of Radiology at the Georgetown University Medical Center that focuses on the development of advanced medical imaging technologies and information systems ². It was established in the 1980s and 1990s and was led by Seong K. Mun ³. Project Argus, on the other hand, is a global detection and tracking system for the early detection of biological events ⁴. It was started on Earth Day, April 21, 1996, with just five operational radio telescopes ⁴.

- 1  govinfo
- 2  idealist
- 3  georgetown
- 4  courthousenews



What is the outcome of the lawsuit between Georgetown College and the former employees over Project Argus patent rights

📄 PERPLEXITY

Georgetown College sued two former employees who refused to give up their patent rights to inventions for "Project Argus," a federally funded global pandemic warning system ¹. The outcome of the lawsuit is unclear, as there are no recent reports on the case. However, the lawsuit suggests that Georgetown College claims ownership of the patent rights to Project Argus ¹. It is possible that the case was settled out of court or is still ongoing. There are no further details on the outcome of the lawsuit.

- 1  courthousenews

Who are the key researchers involved in Project Argus at Georgetown University

📄 PERPLEXITY

Jeffrey Collmann is one of the key researchers involved in Project Argus at Georgetown University ¹. Collmann helped found Project Argus, an award-winning biosurveillance program ¹. However, it is unclear who else was involved in the project, as there are no further details on the researchers involved. The project began on Earth Day, April 21, 1996, with just five operational radio telescopes ¹. The scope of the project had expanded by November 2000 ¹. It is unclear if the project is still active at Georgetown University, as there are no recent reports on the project. However, there is a company called Project Argus that provides supply chain solutions ² ³.

What is the significance of Project Argus in the field of biosurveillance?

📄 PERPLEXITY







Project Argus is a biosurveillance program that was established as a prototype research effort to explore the use of indicators to detect and track biological events, crises, and disasters ¹. The program was founded by Jeffrey Collmann, who currently works with the Office of the Senior Vice President of Research at Georgetown University ² ³. The program is significant in the field of biosurveillance because it is a global detection and tracking system for the early detection of biological events ⁴. The Project Argus Biosurveillance Doctrine was developed to ensure that ethical and legal principles guide the collection and handling of information ⁵. An integrated biosurveillance program is vital to help protect the homeland from bioterrorism, unintentional introductions (e.g., Foot-and-Mouth Disease), and naturally occurring biological events, such as pandemic influenza ¹. Biosurveillance refers to monitoring for potential signs of biological events with the intent of early detection of that event to permit the timely response to mitigate consequences ¹. Should an event occur, biosurveillance and detection allow the monitoring of an outbreak as it happens and provide accurate situational awareness to first responders ¹.

¹ fas ² georgetown ³ georgetown ⁴ nih ⁵ academia

Who is Ellen P Carlin and what is her connection to Georgetown University and EcoHealth Alliance?

↳ PERPLEXITY

Ellen P. Carlin is a veterinarian and Assistant Research Professor at the Center for Global Health Science and Security at Georgetown University ¹ ² ³ ⁴. She has a primary faculty appointment within the Department of Microbiology and Immunology at Georgetown University ². Her research interests are in zoonotic disease, global health security, and One Health approaches to disease prevention and control ⁵. Carlin is also a Research Fellow and Senior Health and Policy Specialist at EcoHealth Alliance, a non-profit organization that focuses on the intersection of human, animal, and environmental health ¹ ⁵ ⁶. At EcoHealth Alliance, Carlin works on projects related to zoonotic disease surveillance, risk assessment, and policy development ⁵ ⁶. She received a bachelor's of science in biology from the College of Mount Saint Vincent and a doctorate in veterinary medicine from Cornell University ⁶.

- ¹  georgetown
- ²  georgetown
- ³  twitter
- ⁴  linkedin
- ⁵  researchgate
- ⁶  ecohealthalliance

Has Ellen Carlin collaborated with any other institutions or organizations on her research

↳ PERPLEXITY

Yes, Ellen Carlin has collaborated with other institutions and organizations on her research. Here are some examples:

- Smithsonian Conservation Biology Institute: Carlin is a research associate with the Smithsonian Conservation Biology Institute, where she works with the Global Health Program to develop research and capacity ¹.
- Parapet Science & Policy: Carlin is a consultant with Parapet Science & Policy, a consulting firm that provides scientific and policy expertise to government agencies, non-profit organizations, and private companies ².
- EcoHealth Alliance: Carlin is a Research Fellow and Senior Health and Policy Specialist at EcoHealth Alliance, where she works on projects related to zoonotic disease surveillance, risk assessment, and policy development ¹ ³ ⁴.
- Georgetown University: Carlin is an Assistant Research Professor at the Center for Global Health Science and Security at Georgetown University, with a primary faculty appointment within the Department of Microbiology and Immunology ⁵ ⁶. At Georgetown, Carlin conducts research on zoonotic disease, global health security, and One Health approaches to disease prevention and control ³.



Overall, Carlin has collaborated with a variety of institutions and organizations on her research, including the Smithsonian Conservation Biology Institute, Parapet Science & Policy, EcoHealth Alliance, and Georgetown University.

- ¹  ecohealthalliance
- ²  linkedin
- ³  twitter
- ⁴  acrl
- ⁵  researchgate

How is Ellen Carlin connected to William Karesh?

PERPLEXITY

Ellen Carlin is connected to William Karesh through their work at EcoHealth Alliance. William Karesh is the Executive Vice President for Health and Policy at EcoHealth Alliance ¹, while Ellen Carlin is a Research Fellow and Senior Health and Policy Specialist at the same organization ². Both Karesh and Carlin work on projects related to zoonotic disease surveillance, risk assessment, and policy development ¹ ².

- 1  researchgate
- 2  ecohealthalliance

What is the connection between William Karesh and Georgetown University

PERPLEXITY

There is no information in the provided search results about a direct connection between William Karesh and Georgetown University. However, both Karesh and Ellen Carlin work on zoonotic disease research and policy development, and Carlin is an Assistant Research Professor at the Center for Global Health Science and Security at Georgetown University ¹ ². It is possible that Karesh has collaborated with Georgetown University researchers on zoonotic disease research, but there is no information in the provided search results to confirm this.

- 1  georgetown
- 2  researchgate

What is William Karesh's connection to "One Health"

⌵ PERPLEXITY

William Karesh is a champion of the "One Health" approach, which is an integrated approach to animal, human, and environmental health ¹ ² ³. He is an internationally recognized authority on One Health and has been involved in One Health initiatives in various countries, including Brazil, Chile, and Colombia ¹ ⁴. Karesh is the EPT Partner Liaison for the USAID Emerging Pandemic Threats PREDICT-2 program, which is focused on predicting and preventing pandemics ⁵. He has also co-authored articles on the importance of One Health and related concepts, such as Planetary Health and EcoHealth, in addressing complex health threats ⁶.

1  nih

2  foreignaffairs

3  genevaenvironmentnetwork

4  frontiersin

What are some notable achievements or initiatives related to One Health that William Karesh has been involved in


📄 PERPLEXITY

William Karesh has been involved in several notable achievements and initiatives related to One Health, including:

- **Coining the term "One Health":** In 2003, Karesh coined the term "One Health" to describe the interdependence of healthy ecosystems, animals, and people ¹. This term has since become widely used in the field of public health and has helped to promote a more integrated approach to health.
- **USAID Emerging Pandemic Threats PREDICT-2 program:** Karesh is the EPT Partner Liaison for the USAID Emerging Pandemic Threats PREDICT-2 program, which is focused on predicting and preventing pandemics ². This program has been instrumental in identifying and responding to emerging infectious diseases, including COVID-19.
- **Wildlife Disease Association:** In 2019, Karesh was awarded the Wildlife Disease Association's highest honor for his contributions to the field of One Health implementation ³. This award recognized Karesh's leadership in promoting a more integrated approach to health and his work on zoonotic disease surveillance and control.


- Co-authoring articles on One Health: Karesh has co-authored articles on the importance of One Health and related concepts, such as Planetary Health and EcoHealth, in addressing complex health threats ⁴. These articles have helped to raise awareness of the need for a more integrated approach to health and have provided guidance on how to achieve this goal.
- EcoHealth Alliance: Karesh is the Executive Vice President for Health and Policy for EcoHealth Alliance, where he works on projects related to zoonotic disease surveillance, risk assessment, and policy development ⁵. EcoHealth Alliance is a non-profit organization that focuses on the intersection of human, animal, and environmental health, and Karesh's work at the organization has helped to promote a more integrated approach to health.

1  biodefensecommission

2  ecohealthalliance

3  ecohealthalliance

4  foreignaffairs

5  aspeninstitute

What connections are there between "One Health" and the Bill and Melinda Gates Foundation?

📄 PERPLEXITY

There are several connections between "One Health" and the Bill and Melinda Gates Foundation, as evidenced by the provided search results:

- Funding: The Bill and Melinda Gates Foundation has provided funding for One Health initiatives, such as the One Health Neglected Zoonotic Disease and Fellowship Fund Support ¹.
- Grants: The Gates Foundation has also provided grants to organizations like the Consortium of Universities for Global Health to support One Health initiatives ².
- Interest: The Gates Foundation has expressed interest in the One Health approach and its potential to improve global health ³ ⁴.
- Meetings: The Ohio State Global One Health Initiative team has met with the Bill and Melinda Gates Foundation core team members to discuss One Health research approaches ⁵.

Overall, the Bill and Melinda Gates Foundation has shown interest in and provided support for One Health initiatives, recognizing the interconnectedness of human, animal, and environmental health.



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Security &
Global Affairs



William Karesh

EXECUTIVE VICE PRESIDENT; ECOHEALTH ALLIANCE, SOCRATES PROGRAM



Dr. William (Billy) Karesh is the Executive Vice President for Health and Policy for EcoHealth Alliance.

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Dr. William (Billy) Karesh is the Executive Vice President for Health and Policy for EcoHealth Alliance. He serves as the inter-project liaison for the USAID Emerging Pandemic Threats PREDICT-2 program (a \$140 Million effort to prevent infectious diseases in 30 countries) and is a member of World Health Organization’s IHR Roster of Experts. Dr. Karesh also serves as the President of the World Organization for Animal Health (OIE) Working Group on Wildlife. In 2016, he was appointed as a member of the Council on Foreign Relations.

Dr. Karesh has pioneered initiatives focusing attention and resources on solving problems created by the interactions among wildlife, people, and their animals. In 2003, he coined the term “One Health” to describe the interdependence of healthy ecosystems, animals and people and the term has been adopted by many organizations, including the United Nations and the World Bank, in local and global health efforts. Dr. Karesh has created dozens of initiatives to encourage linkages among public health, agriculture and environmental health agencies and organizations around the world. He has personally lead programs and projects in over 45 countries, covering terrain from Argentina to Zambia.

In addition to his work in the private non-profit sector, Dr. Karesh has also worked for the USDA, DOD and DOI. He served as a consultant for the Food and Agriculture Organization of the U.N., and is currently on the Steering Committee of OFFLU (OIE-FAO Network of Expertise for Animal Influenzas). Dr. Karesh is internationally recognized as an authority on the subject of animal and human health linkages and wildlife. He has published over one hundred and eighty scientific papers and numerous book chapters, and written for broader audience publications such as *Foreign Affairs*.





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News

Important One Health Message from the Bill & Melinda Gates Foundation

September 11, 2013

Important One Health Message from the Bill & Melinda Gates Foundation

"Guided by the belief that every life has equal value, the Bill & Melinda Gates Foundation works to help all people lead healthy, productive lives. Our [Grand Challenges Explorations](#) program fosters early-stage discovery research to expand the pipeline of ideas for solving our greatest global health and development challenges. Launched in 2008 with a \$100 million commitment from the foundation, Grand Challenges Explorations grants have already been awarded to more than 850 researchers from more than 50 countries. Until November 12, 2013, we are accepting applications on five topics, including ["One Health" Concept: Bringing Together Human and Animal Health for New Solutions](#).



Gates Foundation Initiative

Overview

In 2018 CUGH secured a grant from the [Bill and Melinda Gates Foundation \(BMGF\)](#) to work with the US academic community to increase support for US leadership and funding for global health. To achieve this objective, CUGH collaborated with its members, and CEPH-accredited institutions, to inform Congresspersons and State legislators as well as the general public on the value of global health to their state and the nation. As part of this project, CUGH connected elected officials with

Our Work

Past Projects



Sustaining Technical and
Analytic Resources (STAR)
Project

▸ [Gates Foundation](#)

Collaboration: The Ohio State Global One Health Initiative team has met with the Bill and Melinda Gates Foundation core team members to discuss One Health research approaches ³. The Gates Foundation also collaborates with partners in over 130 countries to address global health issues, including One Health ⁴ ⁵.



Kahn-Kaplan-Monath
7,739 Tweets



Following

impakter.com
One Health and Gender: Why The Two Need To Become One - Impak...
One Health and Gender should be linked and the opportunity to integrate them comes up this fall at the United Nations General ...

 1 4 321

**Kahn-Kaplan-Monath** @OneHealthNews · Jun 15
Earth Future: Time for a Global 'Reset'! peah.it/2023/06/12331/

 1 74

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 69

**Kahn-Kaplan-Monath** @OneHealthNews · Jun 15
UAE to host the first-ever One Health conference in MEA wam.ae/en/details/139... via [@wamnews_eng](https://twitter.com/wamnews_eng)



What connection to the PREDICT program is there with the CIA?

↘ PERPLEXITY

There is a connection between the PREDICT program and the CIA, as the program has been accused of having ties to the CIA. The PREDICT program is part of the USAID's Emerging Pandemic Threats program and is led by the UC Davis One Health Institute ¹. The program seeks to identify new emerging infectious diseases that could become a threat to human health by focusing on wildlife that are most likely to carry zoonotic diseases ². However, in 2020, the program was shut down by the Trump administration, and it was reported that the program had been accused of having ties to the CIA. The accusations were based on the fact that the PREDICT program had worked with the Defense Threat Reduction Agency, which is part of the Department of Defense and has been known to work with the CIA. However, the PREDICT program has denied any ties to the CIA and has stated that its work is focused solely on public health.

1  predict

2  ecohealthalliance

Is there any evidence of CIA involvement in the PREDICT program

🔗 PERPLEXITY

There is no conclusive evidence of CIA involvement in the PREDICT program. However, there have been accusations of ties between the PREDICT program and the CIA. The accusations were based on the fact that the PREDICT program had worked with the Defense Threat Reduction Agency, which is part of the Department of Defense and has been known to work with the CIA ¹. The PREDICT program has denied any ties to the CIA and has stated that its work is focused solely on public health ². While the CIA has been involved in disease intelligence and analysis dedicated to uncovering epidemics, such as Project IMPACT in the mid-1960s ³, there is no evidence that the CIA has been directly involved in the PREDICT program.

- 1🔒cia
- 2🏠go
- 3🌐predict

What is the Project IMPACT and how is it related to disease intelligence

🔗 PERPLEXITY

Project IMPACT was a CIA program that was among the first in "disease intelligence," a field of espionage and analysis dedicated to uncovering epidemics ¹. The project aimed to forecast disease problems and epidemics and assess their effects on military and civilian activities ². The program sought to "computerize disease information and derive trends, cycles, and predictions" to monitor the flu's progression ¹. As the disease spread south from China, and as the U.S. was in the middle of the Vietnam War, the CIA also used Project IMPACT to study the effects on the North Vietnamese army and the Viet Cong ¹. The CIA used the data to send "a warning" to "indigenous intelligence teams operating in Laos and Cambodia to take special precautions during these peak influenza periods" ¹.

The PREDICT program, on the other hand, is a USAID initiative that seeks to aggressively pre-empt or combat diseases that could spark future pandemics ³ ⁴. The program aims to strengthen surveillance and laboratory capacities to monitor wildlife and people in contact with wildlife for novel pathogens ⁵. The PREDICT program has been successful in identifying new emerging infectious diseases that could become a threat to human health ⁶. While there is no evidence that the CIA has been directly involved in the PREDICT program, the CIA has been involved in disease intelligence and analysis dedicated to uncovering epidemics, such as Project IMPACT in the mid-1960s ¹.

- 1🏠go
- 2🔒cia
- 3🌐usaid
- 4🌐usaid
- 5🌐usaid
- 6🌐usaid

services and disease reporting in rural areas was a logical outgrowth of this massive epidemic. Whether the ensuing decline of the disease was due to the extensive use of sulfadiazine or to the normal decline of the epidemic cycle was never ascertained. It was followed by other predicted disease outbreaks (i.e., hepatitis, measles), and a recurrence of a much less severe meningitis epidemic in the winter of 1967-1968. As a postscript, China's failure to prevent and control the spread of diseases was viewed by the USSR as a fundamental weakness of the Chinese health services and the Soviet Ministry of Health abruptly rescinded the 1960 Sino-Soviet agreement on mutual abolition of vaccination requirements for travellers between these countries.

Project IMPACT went global in the summer of 1968 when a new strain of influenza rolled out of China and within a short period of time affected one out of every four persons in the world. The strain was not an unusually lethal one but it was only by chance that it was not. Again, various Agency sources provided the first indication of the beginning of this worldwide pandemic when the disease moved from China via travellers to Hong Kong in late June. An estimated 500,000 cases resulted in Hong Kong alone including 30 percent of the personnel at the American Embassy. At this time a unique opportunity was available to review statistical data on influenza (a program to computerize disease information to derive trends, cycles and predictions had already been initiated under a CIA Project called BLACKFLAG); the current epidemic in Hong Kong was causing the highest incidence since the first Asian Type A2 epidemic of 1957. While the epidemic appeared to be progressing in a new way, initial

What was the CIA's Project BLACKFLAG?

📄 PERPLEXITY

Project BLACKFLAG was a CIA program that tracked the spread of disease in the Soviet Union and North Vietnam and issued regular analyses of the political situation ¹ ². It was part of the CIA's "disease intelligence" program, which was among the first in the field of espionage and analysis dedicated to uncovering epidemics ¹ ². However, there is no further information in the provided search results about the specific objectives or activities of Project BLACKFLAG.

It is important to note that the term "black operation" or "black op" is used to describe covert or clandestine operations by government agencies, military units, or paramilitary organizations ³. The term "black" may also be used as a generic term for any government activity that is hidden or secret ³. For example, in the United States, some activities by military and intelligence agencies are funded by a classified "black budget," of which the details, and sometimes even the total, are hidden from the public and from most congressional oversight ³. However, this is not directly related to the CIA's Project BLACKFLAG.

There are also other projects and programs named Project BLACKFLAG that are unrelated to the CIA's Project BLACKFLAG.

🚩 📄 📁 📧

How did Project BLACKFLAG track the spread of the disease in the Soviet Union and North Vietnam

📄 PERPLEXITY

Project BLACKFLAG tracked the spread of disease in the Soviet Union and North Vietnam and issued regular analyses of the political situation ¹ ². The program sought to "computerize disease information and derive trends, cycles and predictions" to monitor the flu's progression ². The CIA was also able to warn its teams of operatives abroad through BLACKFLAG ³. However, there is no information in the provided search results about how Project BLACKFLAG tracked the spread of disease in the Soviet Union and North Vietnam.

It is important to note that the CIA's Project IMPACT, which was merged with BLACKFLAG, aimed to forecast disease problems and epidemics and assess their effects on military and civilian activities ⁴. The program sought to strengthen surveillance and laboratory capacities to monitor wildlife and people in contact with wildlife for novel pathogens ⁵. The program has been successful in identifying new emerging infectious diseases that could become a threat to human health ⁵.

How did Project BLACKFLAG use computerized disease information to derive trends and predictions

↗ PERPLEXITY

According to the provided search results, Project BLACKFLAG used computerized disease information to derive trends and predictions. The program aimed to "computerize disease information and derive trends, cycles and predictions" to monitor the flu's progression ¹. However, there is no further information in the provided search results about how Project BLACKFLAG specifically used computerized disease information to derive trends and predictions.

It is important to note that the CIA's Project IMPACT, which was merged with BLACKFLAG, aimed to forecast disease problems and epidemics and assess their effects on military and civilian activities ¹ ². The program sought to "computerize disease information and derive trends, cycles, and predictions" to monitor the flu's progression ¹. The program also sought to strengthen surveillance and laboratory capacities to monitor wildlife and people in contact with wildlife for novel pathogens ³. The program has been successful in identifying new emerging infectious diseases that could become a threat to human health ³.

1



2



cia

3



cdc

Project Impact: 'Disease intelligence' and how the CIA traced epidemics out of Cold War Asia

When a new flu strain emerged in Hong Kong, a CIA program "went global."

By [Lee Ferran](#)

June 20, 2020, 4:00 AM



Darrell M. Blocker, a former senior CIA officer who was head of the agency's Africa Division during the Ebola crisis in 2014, said the CIA's mission in disease intelligence is similar today as it was more than a half-century ago and is twofold: Uncovering what's really happening on the ground in countries during epidemics that don't like to share that information and attempting to predict what effect it could have on U.S. interests in the region.

"There's a side to the [disease] research they don't want people to know about. That's where the intelligence comes in," said Blocker, now an ABC News contributor. A spokesperson for the CIA declined to comment for this report.

Blocker said now the U.S. intelligence community can call on its vast, 17-organization-strong apparatus to assess what a disease is doing and how local governments are reacting. But in the mid-1960s, a young CIA was only then starting to appreciate the value of disease intelligence. According to the 1972 declassified CIA article titled "[Intelligence Implications of Disease](#)," it began with Project IMPACT.

"The concept of this project -- forecasting disease problems and epidemics, and the assessment of their effects on military and civilian activities -- had hardly scratched the surface of implementations in the CIA's Office of Scientific Intelligence (OSI); but the opportunity was present in December 1966," the article said.

"The concept of this project -- forecasting disease problems and epidemics, and the assessment of their effects on military and civilian activities -- had hardly scratched the surface of implementations in the CIA's Office of Scientific Intelligence (OSI); but the opportunity was present in December 1966," the article said.

Disease intelligence 'going global'

While IMPACT was able to trace emergence of the meningitis outbreak in the closed communist country, in part by simply observing the movements of the Red Guard from one province to the next, it wasn't until the next outbreak, only months away, that the program expanded and "went global."

That's when a new strain of influenza appeared in Hong Kong and eventually snaked its way around the world. The virus "affected" one in four people on the planet, according to the CIA report. The 1968 flu pandemic is believed to have killed as many as 1 million people worldwide, including 100,000 in the U.S., as [per the Centers for Disease Control and Prevention](#).

Disease intelligence 'going global'

While IMPACT was able to trace emergence of the meningitis outbreak in the closed communist country, in part by simply observing the movements of the Red Guard from one province to the next, it wasn't until the next outbreak, only months away, that the program expanded and "went global."

That's when a new strain of influenza appeared in Hong Kong and eventually snaked its way around the world. The virus "affected" one in four people on the planet, according to the CIA report. The 1968 flu pandemic is believed to have killed as many as 1 million people worldwide, including 100,000 in the U.S, as [per the Centers for Disease Control and Prevention](#).

To monitor the flu's progression, Project IMPACT folded in an ongoing CIA effort known as BLACKFLAG, which sought to "computerize disease information and derive trends, cycles and predictions."

Within weeks, scientists were able to determine it was, indeed, a new strain of influenza, which they named Hong Kong/A2/68. (While the CIA study, citing "various [Central Intelligence] Agency sources," states flatly that the virus "moved from China via travelers to Hong Kong," a [World Health Organization report](#) from 1969 on the virus' origins says it is "not certain" it came from mainland China.)

As experts gathered information on the new virus, the World Health Influenza Center in London made a dire prediction.

"The emergence of a new strain [of influenza] occurs every 10-15 years and together with rapid transportation, and in the absence of specific vaccines, leads us to believe that the disease may cause extensive outbreaks throughout the world in the coming months," the center said, according to the CIA study.

transportation, and in the absence of specific vaccines, leads us to believe that the disease may cause extensive outbreaks throughout the world in the coming months," the center said, according to the CIA study.

Stumbles in the Soviet Union, warnings in Vietnam

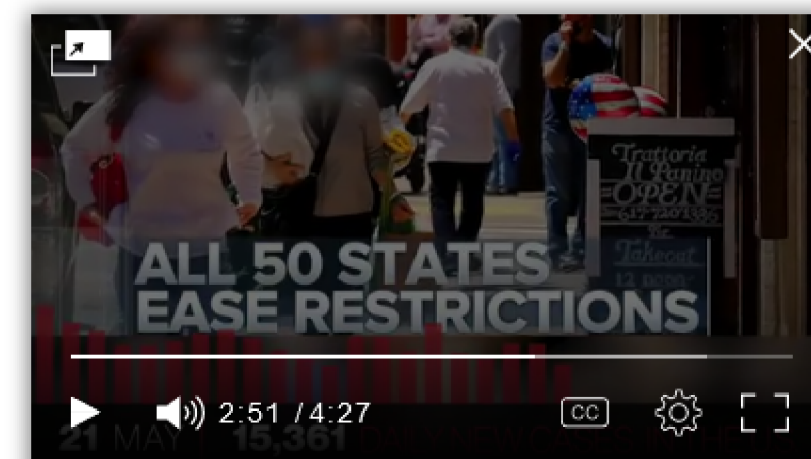
Though the center's warning discussed the "rapid transportation" of people, at the time it was still predicted that it would take some seven months for the new flu to hit the then-Soviet Union, America's arch-nemesis in the Cold War and the focus of so much CIA attention already.

Still, the Soviets weren't able to prepare, the CIA article said.

"[T]he Soviets continued to vaccinate the urban population (about 75 percent) with the standard A2 vaccine which was shown even in August, to have very little protective value against [the] Hong Kong flu (this decision later was reported to be based on their inability to make the new vaccine in less than a year and their gamble that A2 vaccine would help)," the report said. "By late January, the flu was present in many Soviet cities and incidence rates began to increase sharply."

The Soviets hid information about the disease and purportedly interfered with the efforts of health care workers on the ground, according to the study.

In an early echo of the Trump administration's attempts to brand the current novel coronavirus the "Wuhan virus," the Soviets reportedly referred to the disease as "Mao's flu," in a reference to the then-leader of the Chinese Communist Party, Mao Zedong.



Reopened for business: Here's how states responded to coronavirus in May



A lab assistant inoculates fertile eggs with Hong Kong influenza virus at a drug company in West Point, Pa., Nov. 20, 1968. This is one step in the production of the much needed flu vaccine.

Getty Image, FILE

As the disease spread south from China, and as the U.S. was in the middle of the Vietnam War, the CIA also used Project IMPACT to study the effects on the North Vietnamese army and the Viet Cong.

"Staff personnel of the Special Assistant/Vietnam Affairs (SA/VA) were consulted, and together with their data on traffic routes, troop concentration, and locations of waystations (Binh Trams), made it possible to construct a model of the direction of the influenza epidemic," the CIA article said.

With that data and by monitoring reports of sickness and military requests for medicine, the CIA determined that "incapacitation rates ranged from about 40 to 70 percent and there was very good evidence that except for the isolation and quarantine of patients, no capability existed to specifically protect their military personnel by mass vaccinations."

Using the data, the CIA also sent "a warning" to "indigenous intelligence teams operating in Laos and Cambodia to take special precautions during these peak influenza periods."






In the end, the CIA report suggested that Project IMPACT was most successful in simply showing the value of the aggregation of data to help predict the impact of outbreaks.

"Disease intelligence can provide an initiating and vital role in the more familiar political, military and economic categories of intelligence," it says.

What are some current One Health research projects or initiatives that William Karesh is leading or involved in

📄 PERPLEXITY

There is no information in the provided search results about specific One Health research projects or initiatives that William Karesh is currently leading or involved in. However, Karesh is the Executive Vice President for Health and Policy at EcoHealth Alliance, where he works on projects related to zoonotic disease surveillance, risk assessment, and policy development ¹ ² ³. He is also the EPT Partner Liaison for the USAID Emerging Pandemic Threats PREDICT-2 program, which is focused on predicting and preventing pandemics ². Karesh has been involved in One Health initiatives in various countries, including Brazil, Chile, and Colombia ⁴ ⁵. His work has helped to promote a more integrated approach to health on a global scale.

- ¹  nih
- ²  ecohealthalliance
- ³  aspeninstitute
- ⁴  biodefensecommission
- ⁵  ecohealthalliance

Opportunities for Enhanced

DEFENSE, MILITARY, AND SECURITY SECTOR ENGAGEMENT IN GLOBAL HEALTH SECURITY



OPPORTUNITIES FOR ENHANCED DEFENSE, MILITARY, AND SECURITY SECTOR ENGAGEMENT IN GLOBAL HEALTH SECURITY

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BUILDING RESILIENCE TO BIOTHRREATS

*An assessment of unmet core
global health security needs*



BUILDING RESILIENCE TO BIOTHRREATS

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ACKNOWLEDGEMENTS

Numerous individuals contributed to this endeavor. We wish to thank the participants who attended our Washington, D.C. roundtable, many of whom came from great distances to do so, including across the Atlantic Ocean. We thank the World Bank Group for hosting the roundtable and for generously providing additional expertise and collaboration throughout the study process, including through a Knowledge Exchange event. The written report benefitted considerably from the input of many interview participants and peer reviewers. Officials from the government of Liberia were especially gracious with their time to provide valuable country perspective. Jim Desmond and Amanda Andre, both from EcoHealth Alliance, provided significant guidance, coordination, and assistance. The kind help of Barbara Machado and Timothy Bouley from the World Bank was also sincerely appreciated. Finally, we gratefully acknowledge the generous support and enthusiasm of the project's funder, the Smith Richardson Foundation.

In addition to literature research, the following events and experts formed the backbone of this project's information gathering phases, and allowed for substantial deliberation of results and conclusions:

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Opportunities for Enhanced

DEFENSE, MILITARY,
AND SECURITY SECTOR
ENGAGEMENT IN
GLOBAL HEALTH SECURITY

Metrics

- 1.6 billion doses procured
- 582 million doses delivered domestically; 150 million internationally
- Distribution to more than 91,000 sites
- 86 percent of 18+ population received one shot; 207 million Americans fully vaccinated
- 87 percent of ≥65 population, the most vulnerable demographic, fully vaccinated
- 75 million booster doses administered
- 7 million pediatric (ages 5–11) doses administered between 1 November and December 2021
- Managed allocation and ordering of 3.9 million courses of monoclonal antibodies¹⁰

At the time that the CAG was dissolved, the entire U.S. resident population had available and equitable access to a COVID-19 vaccine. The COVID-19 domestic countermeasures production ecosystem was more robust and secure; vaccine waste had been minimized; an IT architecture that provided data on allocations, distribution, and administration was in place; and booster, adolescent, and pediatric vaccine campaigns were ongoing.

Most importantly, the vaccines and therapeutics produced and delivered by the CAG averted an estimated 1.1 million additional COVID-19 deaths and more than 10.3 million additional COVID-19 hospitalizations in the United States as of November 2021.¹¹ This achievement supported and nested with the recovery outlined in the *National Strategy for COVID-19 Response and Pandemic Preparedness* (January 2021).¹² The CAG's efforts arguably saved more American lives than any other DOD effort in U.S. history.

Operation Warp Speed (OWS, since renamed the Countermeasures Acceleration Group -- CAG)

OWS/CAG Timeline

13 March 2020 Declaration of national emergency concerning COVID-19

15 May 2020 Formation of Operation Warp Speed

5 June 2020 MOU signed by the secretary of HHS and secretary of defense to expedite vaccines to 300 million Americans

July 2020 Large-scale efficacy trials begin

11 December 2020* First vaccine receives emergency use authorization (EUA)

24 February 2021 National emergency declaration extended for one year

1 May 2021 OWS was renamed the HHS-DOD COVID-19 Countermeasures Acceleration Group (CAG); new MOU takes effect

10 May 2021* First vaccine receives EUA for adolescents (ages 12–15)

September 2021* CAG assigned mission of managing distribution of therapeutics

1 November 2021* EUA issued for pediatrics (ages 5–11)

19 November 2021* Booster dose authorized for all vaccinated individuals 18 and older

31 December 2021 CAG dissolved, and mission transitioned to the HHS Coordination Operations and Response Element (HCORE)

*The issuance of each EUA and the assumption of the therapeutics mission involved planning and executing the production, delivery, and administration of tens of millions of doses to tens of thousands of individual locations.

**HHS Sec June 2020 signs MOU
to expedite vaccines to 300
Million Americans**

July 2020-efficacy trials

Feb. 2021: 1st vaccine get EUA

May. 2021: 1st vaccine get EUA for 12-15

Nov. 2021: 1st vaccine get EUA for 5-11

Dec. 2021: OWS-CAG- HCORE

ACTIV Accelerating COVID-19 Therapeutic Interventions and Vaccines (est 2020)

FNIH: FOUNDATION FOR THE NATIONAL INSTITUTE OF HEALTH



Who
We Are ▼

Our
Programs ▼

Fighting
Diseases ▼

Po
S

ACTIV Small Animal Models Video Sessions

Click on the speaker's name to see each presentation

- Virus Characteristics: Choosing a strain, passaging and sequencing
 - [Adolfo Garcia-Sastre](#): Virus strain selection and use for COVID-19 Research
- Foundational Practices for Small Animal Models – Mouse, Hamster and Ferret Models
 - Mouse Models
 - [Joanne Turner](#): Transgenic Mouse Models for COVID-19 Research
 - [Ralph Baric](#): Mouse-Adapted Viruses for COVID-19 Research

**FOUNDATION FOR THE
NATIONAL INSTITUTE OF
HEALTH's Animal Model
Presenters 2021, for
Mouse Models is
RALPH BARIC**

https://fnih.org/sites/default/files/2021-07/ACTIV_SARS-CoV-2_Small_Animal_Models_Field_Guide_11.30.20_vF.pdf

<1999 DTRA

DHS:- BioWatch

-Project Bioshield Act-2004

-9/11 Act 2007

Nunn-Lugar Expansion Act 2012

-P3, P2, CWMD

Operation Warp Speed

HHS:PHEMCE, PAHPA, PAHPRIA, PREP ACT

ACCELERATING COVID19 THERAPEUTIC INTERVENTIONS AND VACCINES [ACTIV]

CDA FREQUENTLY ASKED QUESTIONS (FAQ)

https://fnih.org/sites/default/files/pdf/ACTIV_Clinical_and_Preclinical_Candidate_Compound_Portals_Submissions_%20FAQs.pdf

ACTIV Overview

LAUNCH

On April 17, NIH announced the launch of a public-private partnership, **Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)**

MISSION

Develop a coordinated research response to **speed COVID-19 treatment and vaccine options**

<https://fnih.org/what-we-do/programs/activ-partnership>

<https://www.nih.gov/research-training/medical-research-initiatives/activ>



FAQs (1/5)

What is ACTIV?

- **Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)** is a public-private partnership that develops coordinated research strategies for prioritizing and speeding development of the most promising treatments and vaccines for COVID-19.

Why am I being contacted by ACTIV and asked to sign a CDA?

- You submitted a compound via the ACTIV COVID-19 Clinical & Preclinical Candidate Compound Portal and either (1) your survey submission indicated that data essential to evaluate your candidate compound requires a CDA, or (2) your candidate compound was already reviewed, and the panel is asking for additional data for consideration.

Can I make modifications to the CDA?

- The ACTIV CDA is a standard template used for all submissions that require confidentiality agreements. The legal team at FNIH will review any proposed modifications to the CDA, however, this will delay the review process of your candidate compound.

Does the ACTIV prioritization process and CDA guarantee reviewer confidentiality?

- Our reviewers have a confidentiality agreement that binds them to the confidentiality within the CDA.

CDA?




What is a CDA?

CDA is essentially another word for "NDA", or Nondisclosure Agreement. CDA stands for Confidentiality Disclosure Agreement.

What does "CDA" mean in terms of covid-19 vaccines made through the ACTIV program

purposes, but do not want to be disclosed to third parties ¹. In the case of the ACTIV program, a CDA is required for entities that submit compounds for consideration as potential COVID-19 treatments or vaccines ¹ ². The CDA ensures that the submitted compounds and related information are kept confidential and not disclosed to third parties without the consent of the submitting entity ¹ ².

¹  fnih

²  policycommons

ACTIV Stakeholders

ACTIV is being coordinated by the Foundation for the National Institutes of Health (FNIH), and has brought together multiple partners from government, industry and non-profits.

8

Government Partners

20

Industry Partners

3

Non-Profits



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



U.S. FOOD & DRUG
ADMINISTRATION



abbvie

AMGEN

AstraZeneca



Bristol-Myers Squibb



Lilly



evotec



gsk

Johnson & Johnson



MERCK

moderna



NOVARTIS



RHYTHM
THERAPEUTICS

Roche

Genentech

Pfizer



SANOFI

Takeda

NOVAVAX

VIR

BILL & MELINDA
GATES foundation



FRED HUTCH
CURES START HERE

RTI
INTERNATIONAL



Freda C. Lewis-Hall, MD, DFAPA

Former Chief Medical Officer and EVP, Pfizer Inc.



Paul Stoffels, MD

Retired Executive Vice President and Chief Scientific Officer, Johnson & Johnson



Elias Zerhouni, MD

Professor Emeritus, Johns Hopkins University



Solomon H. Snyder, MD

Vice Chairman

Distinguished Service Professor of Neuroscience, Pharmacology & Psychiatry; Solomon H. Snyder Department of Neuroscience at Johns Hopkins University



Charles A. Sanders, MD

Retired Chairman and Chief Executive Officer, Glaxo Inc.

Pfizer

Johnson & Johnson

Johns Hopkins

Johns Hopkins

Glaxo

Robert Califf, FDA

Lawrence Tabak, NIH

EX OFFICIO DIRECTORS

Robert Califf, MD

MACC Commissioner, Food and Drug Administration

Lawrence A. Tabak, DDS, PhD

Performing the Duties of the NIH Director

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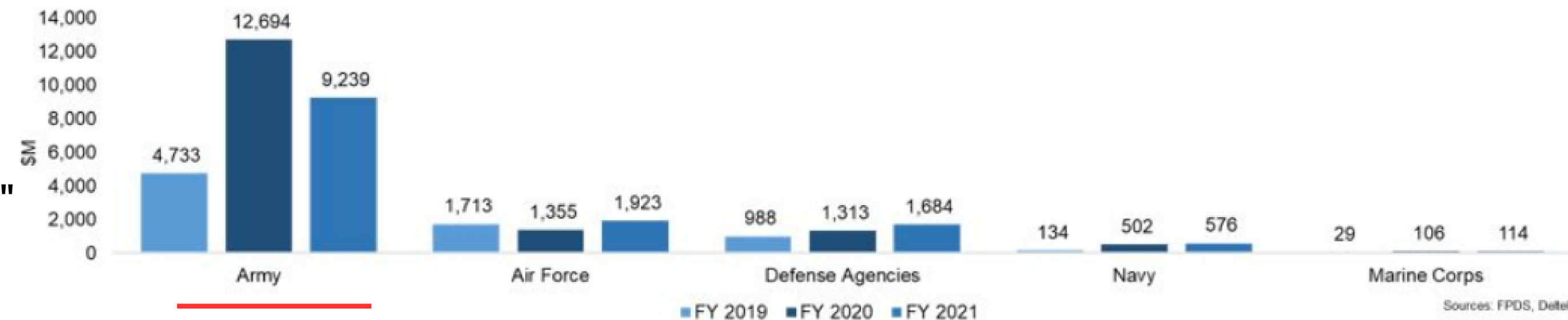
Exhibit 1: FDA's active COVID-19 partnerships with other U.S. government agencies³⁹

Program name	Partners (all include FDA)			Program objectives
RADx	 National Institutes of Health			To speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing
ACTIV	 National Institutes of Health			To develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines through public-private partnerships
Operation Quack Hack				To protect consumers from fraudulent medical products by leveraging Agency expertise and advanced analytics
MOU on food supply				To establish a process by which determinations will be made about circumstances in which USDA could exercise its authority under the DPA over certain FDA-regulated entities to help prevent interruptions at food facilities
Collaboration on antibody tests	 NIAID	 NATIONAL CANCER INSTITUTE		To establish a capability at NIH to evaluate serological tests for developers (including tests already available for use, as well as tests not yet on the market where additional validation data is needed to support an EUA)
Serology studies workshop	 NIAID  National Heart, Lung, and Blood Institute	 NATIONAL CANCER INSTITUTE 	 	To explore strategies to address key scientific opportunities for serology testing to address COVID-19
MOU on advanced manufacturing	 National Institutes of Health			To facilitate information-sharing regarding the use of 3D printing and other advanced manufacturing technologies in the context of personal protective equipment (PPE) and other medical device parts.
Vaccine safety monitoring				To expand safety systems including CDC's V-safe and National Healthcare Safety Network (NHSN)

Total DOD OTA Spending by Organization

When it comes to OTA-related spending, the Army stands head and shoulders above the rest of the DOD. This is true regardless if the good or service being purchased is IT-related or not.

Recommends
companies use
the Army for
OTA's to
"maximize its
earning potential"



The Army outspends all of the rest of DOD on OTAs by a lot every year. The discrepancy reached a high point in FY 2020 when the Army spent nearly four-times as much on its OTA projects than all of the other DOD organizations combined. This ratio of Army to DOD OTA spending decreased to just over two-times in FY 2021 as the Army reduced its spending while other parts of the DOD slightly increased theirs.

The bottom line is that if a company wants to maximize its earning potential doing OTA-related work it really needs to be laser-focused on working with the Army, and then the Air Force, before any other part of the department.

NIH has announced two major research initiatives related to COVID-19. Announced on April 17, 2020, Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) is a public-private partnership with several companies and federal agencies that aims to accelerate research and development on new vaccines and therapeutics by prioritizing vaccine and drug candidates, streamlining clinical trials, coordinating regulatory processes, and leveraging the assets of partners for new products.³¹ The Rapid Acceleration of Diagnostics (RADx) initiative announced on April 29 is a prize competition that aims to incentivize the development of new diagnostics for COVID-19.³²



About MPP

The Medicines Patent Pool (MPP) is a United Nations-backed public health organization working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. Through its innovative business model, MPP partners with civil society, governments, international organizations, industry, patient groups, and other stakeholders, to prioritize and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations. To date, MPP has signed agreements with eleven patent holders for thirteen HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals, a tuberculosis treatment, a long-acting technology and two experimental oral antiviral treatments for COVID-19. MPP was founded by **Unitaid**, which continues to be MPP's main funder. MPP's work on access to essential medicines is also funded by the Swiss Agency for Development and Cooperation (SDC). MPP's activities in COVID-19 are undertaken with the financial support of the Japanese Government and SDC. More information at <https://medicinespatentpool.org/> and follow us on [Twitter](#), [LinkedIn](#) and [YouTube](#).

"The Medicines Patent Pool was established as a landmark initiative to expand access to treatments for priority diseases. Over the last decade, MPP has become a strong partner in global health, working to facilitate access to HIV and hepatitis C medicines in low- and middle-income countries through voluntary licensing and patent pooling. With its impressive track record, MPP has a critical role to play in making affordable versions of patented essential medicines and technologies available to those who need it the most, including for COVID-19."

Dr Tedros Adhanom Ghebreyesus, Director-General, World Health Organization

<https://medicinespatentpool.org/>



INVESTMENT FIRM

Medical CBRN Defense Consort.

Summary

Investments

People

Techno

About

Medical CBRN Defense Consortium was formed in response to the Government's expressed interest for an Other Transaction Agreement (OTA).

Summerville, South Carolina, United States

11-50

Government Office

www.medcbrn.org

98,793

Highlights

Investments

1

Patent pool

In patent law, a patent pool is a consortium of at least two companies agreeing to cross-license patents relating to a particular technology. The creation of a patent pool can save patentees and licensees time and money, and, in case of blocking patents, it may also be the only reasonable method for making the invention available to the public. Competition law issues are usually important when a large consortium is formed.

W More at Wikipedia

Repurposing a Defense Department consortium

Advance Technology International manages contracts and facilitates dealings with the government for several consortia of academics, companies and more, using OTAs.

In March and early April, the Department of Defense talked with ATI about a consortium of academics and companies that it manages called the Medical CBRN Defense Consortium, which is tasked with developing medical countermeasures to threats against the military. The Department of Defense, a partner in Operation Warp Speed, already had an overarching OTA with ATI concerning this group. To expand it for the COVID-19 response was a matter of adding more money and issuing a request for proposals concerning coronavirus vaccines and other COVID-19 items.

Many were OTAs that weakened or excluded [Bayh-Dole clauses](#), which, among other things, allow the government to "march in" and take control of a drug or vaccine if a manufacturer that received federal funding engages in price gouging, for example.

"When asked about whether these contracts could be disclosed to the public under public records requests, he said *it was up to the government.*"

Tuohy says the consortium was established with a flexible mission, adding that OTAs often get a bad rap, but they don't deserve it. Even if the contracts don't include things like the Bayh-Dole protections, he says they often have similar replacement language. When asked about whether these contracts could be disclosed to the public under public records requests, he said it was up to the government. ATI couldn't point to an example of one of its contracts to consortium members being disclosed this way, but this may have happened without it being made aware.

**OTA
for Prototype
Agreement**

**Merck Sharp &
Dohme Corp**

**NATICK: (ACC-Army,
Aberdeen Proving
Grounds MA**

**December 2020
W911QY-21-0-0001
\$355,562,292.00**

OTHER TRANSACTION AUTHORITY FOR PROTOTYPE AGREEMENT

BETWEEN

**Merck Sharp & Dohme Corp (Awardee)
2000 Galloping Hill Rd.
Kenilworth, NJ 07033-1310
DUNS Number: 001317601
CAGE Code: 6B2S4**

And

**NATICK CONTRACTING DIVISION (Government)
15 General Greene Ave.
Natick, MA 01760**

**Effective Date:
Agreement Number:
Total Amount of the Agreement:**

**2 December 2020
W911QY-21-9-0001
\$355,562,292.00**



DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PICATINNY ARSENAL, NEW JERSEY 07806-5000

REPLY TO
ATTENTION OF

21 July 2020

July 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 9
Picatinny Arsenal, NJ 07806

**Army Contracting
Command**

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-11, Objective PRE-20-11 for “COVID-19 Pandemic – Large Scale Vaccine Manufacturing Demonstration” (Pfizer, Inc.)

REF: Prizer Request for Technical Direction Letter, RPP 20-11 under OTA W15QKN-16-9-1002 for Objective PRE-20-11, dated 20 July 2020

Advanced Technology International
ATTN: (b) (6), Sr. Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Pfizer Vaccine

Dear (b) (6),

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued MCDC RPP 20-11 on 09 June 2020. Members of the MCDC submitted proposals in accordance with this RPP. The Government received and evaluated all proposal(s) submitted and a Basis of Selection has been executed, selecting Pfizer, Inc. as the awardee. The Government requests that a Firm-Fixed-Price Project Agreement be issued to Pfizer, Inc. to award this proposal under Other Transaction Agreement W15QKN-16-9-1002, to be performed in accordance with the attached Government Statement of Work (SOW).

Based upon the acceptable update of Pfizer, Inc.’s proposal for “COVID-19 Pandemic – Large Scale Vaccine Manufacturing Demonstration” and 1) The Project Agreement Recipient’s concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and; 3) The price proposed that has been analyzed by the Government, you are hereby directed to issue a Project Agreement to Pfizer, Inc. for the subject project. The total project value has been determined fair and reasonable and Pfizer, Inc.’s proposal has been selected IAW the above referenced Basis of Selection.

The total approved cost to the Government for this effort is not to exceed \$1,950,097,500.00. The break-out of the costs is as follows: \$1,950,000,000.00 to perform project efforts included in the SOW

**ATI
(Advanced
Technology
International)
Contract Manager**

Are there any other companies that have used OTA technology for their COVID-19 vaccines

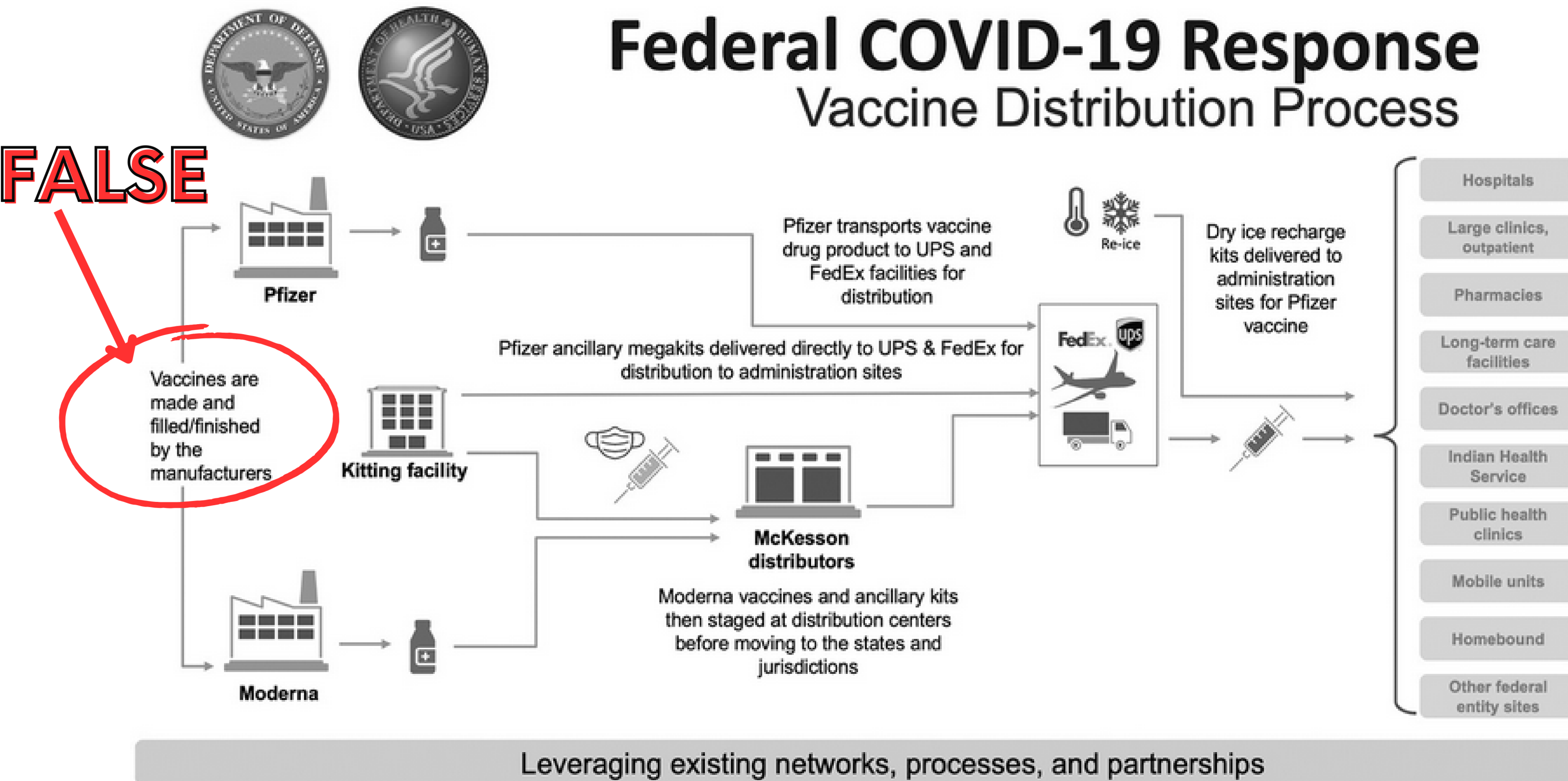
↘ PERPLEXITY

Yes, there are other companies that have used OTA technology for their COVID-19 vaccines. The U.S. government has used Other Transaction Authority (OTA) agreements to work with private companies to develop new technologies or products, including COVID-19 vaccines. Here are some examples:

- Johnson & Johnson: The U.S. government awarded Johnson & Johnson a \$1 billion OTA agreement to develop and manufacture a COVID-19 vaccine ¹. The agreement provided for the delivery of 100 million doses of the vaccine, with an option for the government to purchase an additional 200 million doses ¹.
- AstraZeneca: The U.S. government awarded AstraZeneca a \$1.2 billion OTA agreement to develop and manufacture a COVID-19 vaccine ². The agreement provided for the delivery of 300 million doses of the vaccine ².
- Sanofi and GlaxoSmithKline: The U.S. government awarded Sanofi and GlaxoSmithKline a \$2.1 billion OTA agreement to develop and manufacture a COVID-19 vaccine ³. The agreement provided for the delivery of 100 million doses of the vaccine, with an option for the government to purchase an additional 500 million doses ³.

Overall, OTA agreements have been used by the U.S. government to work with private companies to develop COVID-19 vaccines and other technologies. These agreements provide the government with access to cutting-edge technologies and products that might not be available through traditional procurement methods ⁴.

Figure 2. COVID-19 response and vaccine distribution process



FOR IMMEDIATE RELEASE

October 18, 2022

Contact: HHS Press Office

202-690-6343

media@hhs.gov

HHS Announces Actions to Counter Biological Threats, Enhance Pandemic Preparedness, and Achieve Health Security

The U.S. Department of Health and Human Services (HHS) today announced actions the department will take following National Security Memorandum 15, signed by President Biden, directing implementation of the [2022 National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security - PDF](#).

<https://www.hhs.gov/about/news/2022/10/18/hhs-announces-actions-to-counter-biological-threats-enhance-pandemic-preparedness-and-achieve-health-security.html>

Strengthening early warning and awareness of pandemics and biological threats

HHS will lead efforts to improve early warning of biological threats and data availability to support real-time, evidence-based decision-making, including:

- **Improving disease detection and reporting:** Develop domestic capability to improve detection and reporting of disease outbreaks, conduct rapid genomic sequencing and analysis, and support the development of global systems to share information, data, and samples internationally and across industry sectors. Such improvements are essential to prevent or limit the impact of significant biological incidents, both domestically and internationally.
- **Accelerating advanced detection technologies:** Accelerate research and innovation for advanced biodetection capabilities for clinical and environmental settings, to enable large-scale, affordable, and routine surveillance for novel pathogens.
- **Enhancing hospital data collection:** Maintain and enhance an enduring domestic all-hazards hospital data collection capability to enable comprehensive data reporting for biosurveillance, situational awareness, and emergency response operations at the federal, state, local, tribal, and territorial levels.
- **Improving data analysis to enhance early warning:** Enhance capacity for rapid analysis, modeling, baselining, forecasting, and reporting to monitor and evaluate the health threat landscape, using a One Health approach, and improve early warning capabilities.

"ONE HEALTH"

<https://www.hhs.gov/about/news/2022/10/18/hhs-announces-actions-to-counter-biological-threats-enhance-pandemic-preparedness-and-achieve-health-security.html>

What is Operation Warp Speed and how does it differ from typical R&D?

Operation Warp Speed is a new national program to “accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics.”²⁷ The program is intended to coordinate MCM efforts “between components of HHS, including CDC, FDA, NIH, and BARDA; the Department of Defense; private firms; and other federal agencies.” Its stated goal is to accelerate selected MCM testing while developing manufacturing infrastructure to allow mass distribution faster than would be possible otherwise (see **Figure 1**). Not all government-supported countermeasures will participate in Operation Warp Speed.

The **Department of Defense (DOD)** operates several medical research and MCM development efforts, including through the Congressionally Directed Medical Research Program (CDMRP), the U.S. Army Medical Research and Development Command (USAMRDC), and the Defense Advanced Research Projects Agency (DARPA). For example, DARPA’s Pandemic Prevention Platform program is focused on developing a platform that would aid in the rapid development of new MCMs in response to the identification of any known or unknown infectious threat.¹⁵

CDC, NIH, and FDA participate in the **Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)**, along with DOD, the U.S. Department of Veterans Affairs (VA), the Department of Homeland Security (DHS), and the U.S. Department of Agriculture (USDA). The PHEMCE, under the leadership of ASPR, facilitates interagency coordination and strategy for the development, regulation, and availability of medical countermeasures in preparation for public health emergencies such as infectious disease outbreaks. As required by Public Health Service Act (PHSA) Section 2811,¹⁶ the PHEMCE assesses and updates a strategy plan annually for MCM preparedness.¹⁷

GAO Highlights

Highlights of [GAO-23-105713](#), a report to congressional committees

Why GAO Did This Study

The COVID-19 pandemic and other recent public health emergencies highlight the threat of widespread illness and death posed by new and emerging infectious diseases. GAO has designated HHS's leadership and coordination of public health emergencies as a high-risk area due to the need to be prepared for, and effectively respond to, future public health threats.

The CARES Act includes a provision for GAO to report on its ongoing monitoring and oversight efforts related to the COVID-19 pandemic. This report examines (1) how HHS used CIADM program funds prior to and during the COVID-19 pandemic, (2) what challenges affected the CIADM program's effectiveness in developing and manufacturing countermeasures, and (3) how HHS plans to use its new program model to address the challenges of the CIADM program.

To address these objectives, GAO

February 2023

PUBLIC HEALTH PREPAREDNESS

HHS Should Plan for Medical Countermeasure Development and Manufacturing Risks

What GAO Found

In 2012, the Department of Health and Human Services (HHS) established a program to improve domestic infrastructure and expertise to produce medical countermeasures—such as drugs and vaccines—in response to public health emergencies. This program, known as the Centers for Innovation in Advanced Development and Manufacturing (CIADM), was originally composed of three sites responsible for, among other things, rapidly producing countermeasures for a pandemic. During the period prior to the COVID-19 pandemic, HHS funded the sites to produce small batches of drug substances for other manufacturers. During the COVID-19 pandemic, HHS provided increased funding to reserve capacity to produce products at a larger scale to aid the pandemic response. However, HHS said that the sites faced challenges reliably producing products at a larger scale, such as poor quality control, that led to the eventual shutdown of one site due to cross-contamination.

An internal HHS review found that a lack of regular manufacturing work from either HHS or other manufacturers prevented the sites from developing the capability to rapidly produce countermeasures at a large scale as the program intended. HHS and site officials identified several reasons for this underuse, including a lack of dedicated funding from HHS and challenges attracting external manufacturers to use the sites for countermeasure production.

HHS is ending the CIADM program and plans to transition to a new program model—the National Biopharmaceutical Manufacturing Partnership (BioMaP). BioMaP is early in its development, and it is unclear how BioMaP will address some of the challenges faced by the CIADM program, as in the following examples.



examined HHS documents and leading practices for managing program risks and interviewed and reviewed written correspondence with representatives from HHS and the three CIADM sites.

What GAO Recommends

GAO is recommending that HHS incorporate into the development of its new program model an approach to systematically assess, and respond to, known challenges and risks associated with advanced development and manufacturing of medical countermeasures. We provided a draft of this report to HHS for review and comment. HHS concurred with our recommendation.

View [GAO-23-105713](#). For more information, contact Mary Denigan-Macauley at (202) 512-7114 or deniganmacauleym@gao.gov.

- BioMaP is expected to use a different contracting structure intended to provide more incentives for industry partners to participate. However, this different structure requires additional expertise to manage effectively. Moreover, HHS told GAO that its contracting staff had previously faced resource challenges using this different contracting structure for other programs during the COVID-19 pandemic. HHS officials said in April 2022 that the agency has half the contracting staff needed to manage its contracting portfolio. This creates the risk that the agency may not have enough resources and expertise to manage this different structure effectively.
- HHS does not have a sustainable source of funding for the new program model, and it has not yet developed detailed plans or budgets. HHS officials said that, without sustained funding for BioMaP or a similar program, the agency would be unprepared to respond to the next pandemic.

As HHS is developing its plans for a new program model for countermeasure production, incorporating an approach to address these challenges and risks would provide HHS with greater assurance that it can avoid repeating the challenges of the CIADM program.

United States Government Accountability Office

³²For example, as part of the COVID-19 response, the government supported multiple manufacturing technologies during vaccine development in order to mitigate the risk that any one platform or specific vaccine candidate could fail because of problems with safety, efficacy, industrial manufacturability, or scheduling factors. This strategy included two vaccine platforms that had not previously been used in a licensed vaccine, but could theoretically be quickly adapted to COVID-19 and scaled up rapidly (i.e., the mRNA platform and replication-defective live-vector platform), and one platform that had been proven (i.e., the recombinant-subunit-adjuvanted protein platform). For more information, see GAO, *Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges*, [GAO-21-319](#) (Washington, D.C.: Feb. 11, 2021).

<https://www.gao.gov/assets/gao-23-105713.pdf>

FDA Inspections and Current Good Manufacturing Practices for Vaccines

The Food and Drug Administration (FDA) ensures the quality of vaccines marketed in the U.S. by monitoring manufacturing facilities' compliance with current good manufacturing practices. Current good manufacturing practices are FDA regulations that contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a product. See 21 C.F.R. Parts 210 and 211 (2021). FDA considers compliance with current good manufacturing practices as part of its review of new product applications, as well as during post-marketing inspections.

Other Transaction Agreements (OTA) Use During COVID-19

Most of the COVID-19 OTA dollars were obligated in July 2020 and driven by vaccine awards. Of the \$12.5 billion the Departments of Defense, Health and Human Services (HHS), and Homeland Security obligated for COVID-19 OTAs, \$8.9 billion or 71 percent was for vaccine development—including clinical trials—and manufacturing efforts. The remaining \$3.6 billion was for medical research and development and other nonvaccine products and services. HHS obligated at least \$1.6 billion on COVID-19-related OTAs from March 2020 through March 2021—primarily to help accelerate vaccine development and manufacturing. However, this is an underreported figure because HHS misreported its OTAs as procurement contracts. From November 2020 through March 2021, OTA obligations were comparatively not as significant as earlier in the pandemic. This was, in part, because additional vaccine doses were acquired using procurement contracts instead of OTAs.

Source: [GAO-21-501](#). | GAO-23-105713

UNC'S 2021 SYMPOSIUM FOR RESEARCH ADMINISTRATORS

**Agencies
authorized to
fund OTAs**

- Dept of Defense (DoD) – all branches (DARPA, AFRL)
- U.S. Dept of Transportation (DOT)
 - Federal Aviation Administration (FAA)
- U.S. Dept of Homeland Security (DHS)
 - Transportation Security Administration (TSA)
 - DHS Domestic Nuclear Detection Office (DNDO)
- U.S. Dept of Health and Human Services (DHHS)
 - National Institutes of Health (NIH)
- U.S. Dept of Energy
 - DOE Advanced Research Projects Agency-Energy (ARPA-E)
- National Aeronautics and Space Administration (NASA)

What are the 3 types of OTAs?

R&D (Research and Development)

- Medical research
- Pharmaceuticals
- Community engagement

Prototype activities

- Military technology improvements
- Energy development and security research
- Oil and pipeline safety

Production activities

- May follow on after prototype activity is completed



R&D (Research and Development) OTAs

- Used for basic, applied, and advanced research
- Should allow for greater speed, flexibility, and accessibility for research activities
- Reduces the burden of Government regulatory overhead allowing for a more competitive environment within the **commercial** (non-defense) sector
- Can address IP concerns and cost accounting standards by providing terms that may be more desirable to commercial partnerships

Prototype and Production OTAs

- Prototype OTAs allow for projects that are directly relevant to weapons or weapons systems proposed to be acquired or developed by the Department of Defense.
- Production OTAs allow for a non-competitive, follow-on OTA to the prototype agreement that has been successfully completed. Government must give advanced consideration, and notice is to be made of the potential follow-on OTA. Therefore, all solicitations will include a notice that there is the future possibility of a follow-on OTA.

OTA Structures

- OTAs' structure allows the government flexibility to include, amend, or exclude traditional procurement clauses.
- Different OTA structures:
 - Direct relationship between single government agency and provider
 - Joint ventures
 - Partnerships
 - Multiple agencies collaborating to fund an agreement across multiple providers
 - Consortium Pass-through

Other positive considerations for the federal use of an OTA

OTA's do not include onerous contracting obligations found in a federal procurement contract such as:

- Bayh-Dohl Act;
- Buy American Act;
- Contract Disputes Act;
- Truthful Cost or Pricing Act;
- Cost Accounting Standards

National Institutes of Health (NIH) OTA Structure

National Institutes of Health (NIH)

- Direct flow of funds to UNC
- Pass-thru funding to RTI (Contract Research Organization aka CRO)

Department of Defense (DOD) OTA Structure

- Department of Defense typically funds via a Consortium Agreement which is defined as an organized group focusing on a specific technology area (non-profits, academia, or contractors)
- Pass-through consortiums/CRO from which UNC has received funding:
 - Medical Technology Enterprise Consortium (MTEC)
 - Medical CBRN Defense Consortium (MCDC)
 - Nano-Bio Materials Consortium (NBMC)

explain OTAs in the context of medical counter measures

↳ PERPLEXITY

In the context of medical countermeasures, Other Transaction Authorities (OTAs) are a type of procurement contract that can be used to support the development and manufacturing of medical countermeasures ¹ ². Here are some key points to understand about OTAs and medical countermeasures:

- Medical countermeasures (MCMs) are FDA-regulated products (biologics, drugs, devices) that may be used in the event of a potential public health emergency stemming from a terrorist attack with a biological, chemical, or radiological/nuclear material, or a naturally occurring emerging disease ³.
- The FDA works with partners at all levels of government to support MCM-related public health preparedness and response efforts ³.
- OTAs are not required to include terms and conditions that are typically required when using traditional procurement contracts subject to the Federal Acquisition Regulation (FAR) ¹.
- OTAs can be used to support the development and manufacturing of medical countermeasures ¹ ².
- The ultimate purpose of an OTA for medical countermeasures is to develop a countermeasure against a specific disease or condition by rapidly obtaining research and development services ².
- Uncertainty is a common cognitive strategy when dealing with medical countermeasures, and information seeking is an important part of public understanding of medical countermeasures ⁴.

Overall, OTAs are one way that the government can support the development and manufacturing of medical countermeasures in the event of a public health emergency.

OTA's:

Other Transactional Authority

NOT- required to include terms and conditions that are traditionally required for Federal Acquisition Regulations.

what role did the DoD have in the covid-19 vaccines?

The Department of Defense (DoD) played a significant role in the development, manufacturing, and distribution of COVID-19 vaccines in the United States. Here are some key points to understand about the DoD's role in COVID-19 vaccines:

- Since May 2020, federal efforts to speed up the development, manufacturing, and distribution of COVID-19 vaccines have been led by the Departments of Health and Human Services (HHS) and Defense (DoD) through a partnership called Operation Warp Speed ¹ ².
- The DoD COVID-19 Vaccination Plan served as the DoD's integrated global response plan to distribute and administer the COVID-19 vaccine ³.
- The DoD worked with vaccine companies to develop COVID-19 vaccines and made available a sufficient supply for all eligible people in the nation ¹.
- The DoD was involved in the transfer of remaining COVID-19 vaccine manufacturing assets from the DoD to HHS in 2022 ¹.
- In January 2023, Defense Secretary Lloyd J. Austin III rescinded the Pentagon COVID-19 vaccine mandate, affecting thousands of Airmen and Guardians ⁴.

- The DoD was involved in the manufacturing of COVID-19 vaccines through the HHS-DOD COVID-19 Countermeasures Acceleration Group (CAG), which worked with vaccine companies to develop COVID-19 vaccines and made available a sufficient supply for all eligible people in the nation ¹.
- The CAG dissolved and transitioned its responsibilities, including DOD-led vaccine activities, to HHS by December 31, 2021, as required by an April 2021 memorandum of understanding between the two departments ¹.
- DARPA, a research and development agency of the DoD, contributed to preventing future COVID-19 infections through novel vaccine technology ².

What was the organizational structure of Operation Warp Speed

- Operation Warp Speed was a public-private partnership that aimed to coordinate existing efforts with new ones ¹.
- The program was initially funded with about \$10 billion from the CARES Act (Coronavirus Aid, Relief, and Economic Security) passed by the United States Congress on March 27, 2020 ¹.
- The program was led by Dr. Moncef Slaoui, the chief adviser, and General Gustave Perna, the chief operating officer ².
- The organizational chart of Operation Warp Speed revealed a highly structured organization in which military personnel vastly outnumbered civilian scientists ².
- The program had three focus areas: developing and manufacturing vaccines, delivering vaccines, and ensuring safe and effective vaccine administration ³.

Global Monitoring for Disease Outbreaks: Project Argus

Emergency Preparedness and Biodefense Seminar Series

November 29, 2007

Building 50 Conference Center

“Global Monitoring for Disease Outbreaks:
Project Argus”

Dr. James Wilson, Georgetown University Medical Center



00:04 / 1:14:41

Total Running Time – 1:14:42



Link: <https://videocast.nih.gov/watch=6337>

Air date: Thursday, November 29, 2007, 3:30:00 PM

Time displayed is Eastern Time, Washington DC Local

Views: Total views: 361 * This only includes stats from October 2011 and forward.

Category: Special

Runtime: 01:14:42

Description: Dr. Wilson is a faculty member in the departments of pediatrics, radiology, microbiology and immunology at Georgetown University Medical Center, where he directs Project Argus, a global detection and tracking system for the early detection of biological events. His presentation will focus on how non-traditional data can be used to detect outbreaks of human, animal and plant diseases. More information is available at <http://biodefense.georgetown.edu/projects/argus.aspx>

What were the incentives offered to private companies to participate in Operation Warp Speed

The incentives offered to private companies to participate in Operation Warp Speed were designed to encourage faster vaccine development and manufacturing. Here are some key points to understand about the incentives offered to private companies:

- The funding mechanism utilized by Operation Warp Speed was based on incentive rather than government control ¹.
- Private companies were provided with funding and support to develop and manufacture COVID-19 vaccines ².
- The program provided logistical support to ensure the efficient distribution and administration of COVID-19 vaccines ³.
- Private companies were also provided with incentives to encourage faster vaccine development and manufacturing ².
- The benefits for companies who landed an Operation Warp Speed contract went beyond just money, according to one of the companies with a contract ².
- SiO2 Materials Science, an Auburn, Ala.-based company that is making vials for the effort, used its status as an Operation Warp Speed grantee to force a vendor to cut production time from 75 days to just seven. It also leveraged its contract with Warp Speed to get its power turned on in the midst of a massive outage in just minutes ².
- Governments can offer incentives to install extra capacity and stockpile inputs to encourage faster vaccine manufacturing ⁴.

Are there any politicians that have stocks in Moderna?

▾ PERPLEXITY


There have been reports of politicians buying and selling stocks in Moderna, a biotechnology company that has developed a COVID-19 vaccine. Here are some examples:


- A senior aide to Sen. Mitch McConnell made a mid-January purchase of Moderna, Inc., a biotechnology company that had four days earlier announced it would begin developing a coronavirus vaccine ¹.
- Rep. Josh Gottheimer, a Democrat of New Jersey, held Moderna stock. In May 2020, he sold up to \$15,000 worth of his shares ².
- The chancellor, Rishi Sunak, co-founded a hedge fund that has a \$500m investment in Moderna, which accounts for around 20% of all the money it manages, about \$2.5bn ³.
- According to OpenSecrets, Rep. Jim Sensenbrenner (R-Wis.) reported holding between \$1 million and \$5 million in Pfizer stock, which is another company that has developed a COVID-19 vaccine ⁴.
- Consumer Watchdog reported that 38 senators had up to \$13.4 million in pharmaceutical stock, but it is unclear if any of these stocks were specifically in Moderna ⁵.


It is worth noting that not all of these transactions necessarily constitute insider trading or other illegal activities. However, there have been concerns about the potential for conflicts of interest when politicians hold stocks in companies that are involved in developing COVID-19 vaccines or treatments.

1  politico

2  businessinsider

3  theguardian

4  opensecrets

5  consumerwatchdog

which lawmakers have bought or sold Moderna stocks

↘ PERPLEXITY

According to an analysis by Business Insider, at least 75 federal lawmakers held shares of Moderna, Johnson & Johnson, or Pfizer in 2020 ¹. Rep. Josh Gottheimer, a Democrat of New Jersey, was the only other lawmaker who held Moderna stock. In May 2020, he sold up to \$15,000 worth of his shares ¹. Additionally, a senior aide to Sen. Mitch McConnell made a mid-January purchase of Moderna, Inc., a biotechnology company that had four days earlier announced it would begin developing a coronavirus vaccine ². However, it is worth noting that not all of these transactions necessarily constitute insider trading or other illegal activities. It is illegal for lawmakers and aides to trade stocks based on private information, but they are allowed to buy and sell shares based on public information they absorb on Capitol Hill so long as they disclose those trades within 30 days ². The potential for conflicts in stock trading by members of Congress has long drawn criticism, especially when particularly blatant cases emerge ³.

1  businessinsider

2  politico

3  nytimes

was bill and melinda gates involved in Operation Warp Speed?

📄 PERPLEXITY

There is no evidence that Bill and Melinda Gates were directly involved in Operation Warp Speed (OWS), which was a U.S. public-private partnership to accelerate the development, manufacture, and distribution of COVID-19 vaccines, therapeutics, and diagnostics announced by President Trump on May 15, 2020 ¹. However, the Bill & Melinda Gates Foundation has been involved in several initiatives related to COVID-19 vaccine development and distribution, including providing more than \$2 billion to support the global response to COVID-19, investing in deep technical expertise and novel platforms in vaccine development and manufacturing to accelerate innovation for better, faster, and cheaper vaccines, and supporting the Gavi COVAX Advance Market Commitment to help ensure that COVID-19 vaccines are accessible and affordable in low- and middle-income countries ² ³.

1  nih

2 Gf gatesfoundation

3 Gf gatesfoundation



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Project Argus

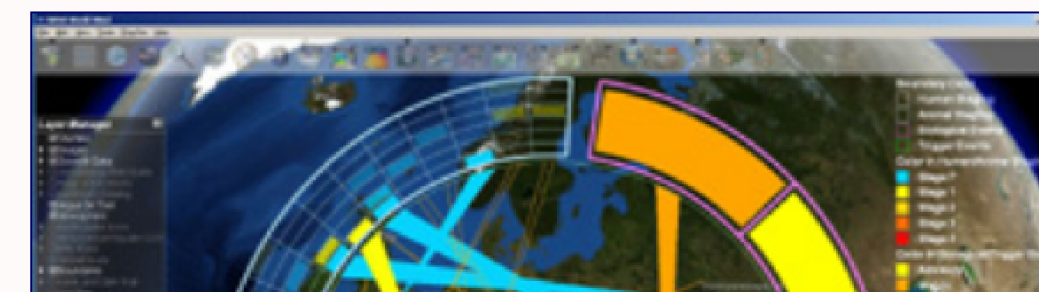


Fig. 1: Air-Transportation Query Page

The frequency of biological events with a potential impact on homeland security is increasing, and current disease surveillance systems in the United States (U.S.) have been inefficient in their capacity to detect these events in a timely fashion. The clear and present danger to the United States spans infectious diseases of humans, animals, and plants.

Indications and Warnings (I&Ws) alert U.S. responders of an imminent bioevent weeks to months in advance. I&Ws are markers occurring globally, outside of U.S. borders, before an outbreak can affect U.S. interests, forces, citizens, or territory, thus allowing the U.S. time to respond. In effect, I&Ws can prime the national response infrastructure by alerting agencies of an evolving threat that could ultimately be catastrophic. Retrospective analyses of major bioevents have demonstrated the presence of multiple I&Ws were present in multiple data sources weeks to months in advance, which were not recognized and utilized properly by the national response community.

For the U.S. to meet present and future biot threats that span agricultural, animal, and human considerations, an integrative strategy for information discovery,





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Project Sentinel

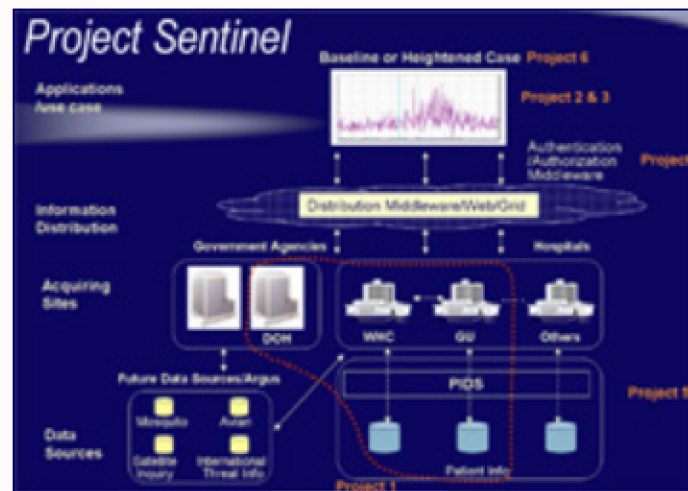


Fig. 1: Project Sentinel Collaboratory

The Project Sentinel Collaboratory, funded by the National Library of Medicine, Georgetown University and the Emergency Departments of MedStar Washington Hospital Center, and MedStar Georgetown University Hospital, will build and deploy a data-centric collaboratory to collect and analyze data from hospitals, clinics, weather services, satellites, mosquito collections, veterinary clinics and other sources in order to develop indications and warnings (I&Ws) of emerging threats to human health. Detection of appropriate I&Ws will allow more time for various authorities to prepare corresponding responses to potential threats.

The Project Sentinel Collaboratory will exploit emerging new concepts in information technology, such as middleware, network weather services, electronic authorization and authentication approaches, and grid services to manage novel disparate data streams and evaluate network-dependent applications. Appropriate use of these tools will enhance interoperability, improve protection of data security, and increase the speed at which essential and useful information can be communicated among authorized users. Initial users of the system will include public health authorities at the DC Department of Public Health, researchers, and physicians from participating hospitals, emergency departments and community clinics. This project is a key part of a prototype integrated biodefense system currently under development by the Division of Integrated Biodefense.

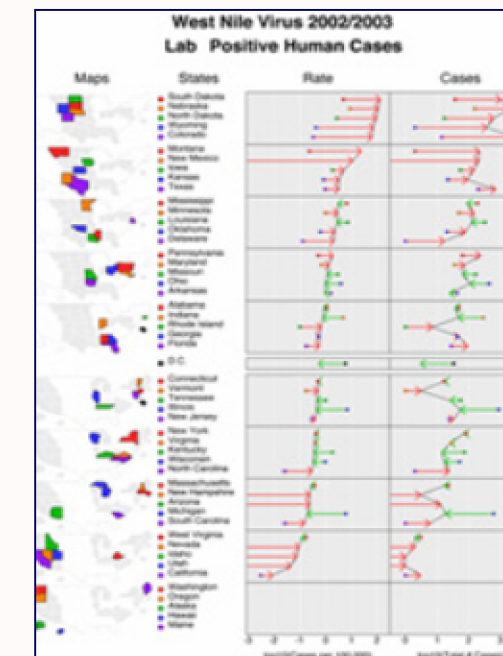


Fig. 2: West Nile Virus Lab Data

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Project Argus

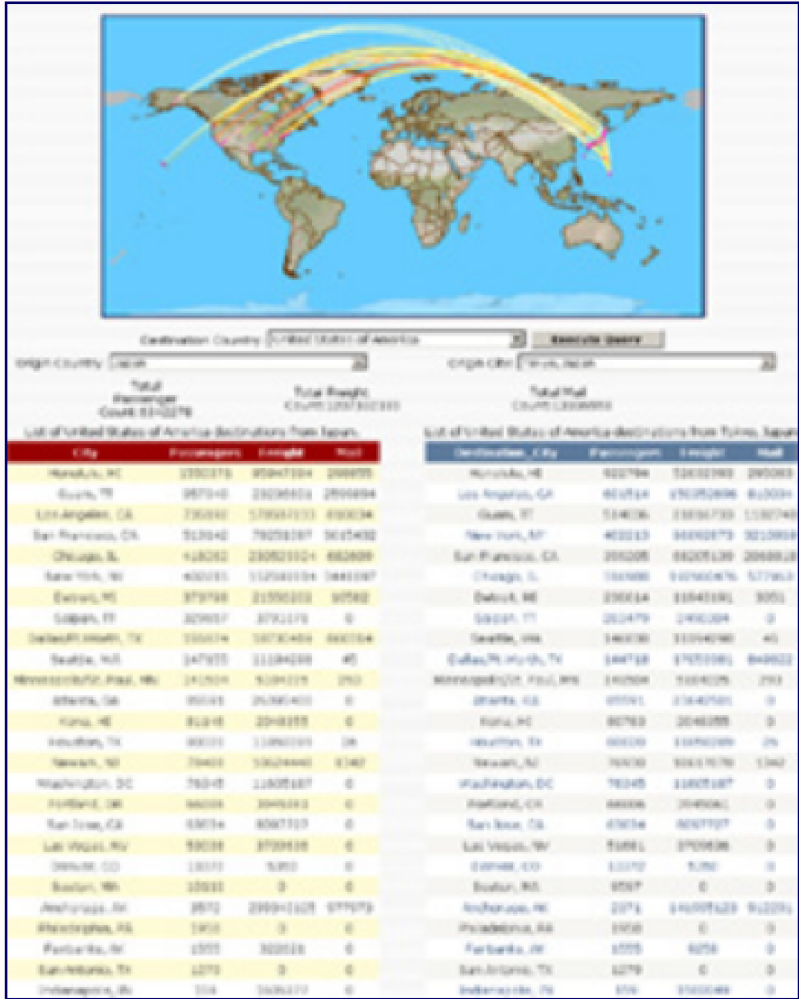


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exploitation, and effective proactive use by the response community is critical. I&Ws provide a key component for integration within the U.S. biosurveillance portfolio, enabling earlier warning potential. Project Argus is the first attempt to integrate I&Ws in effort to detect catastrophic bioevents on an international scale. The Argus system serves as a primer for U.S. countermeasure response plans in the context of a potentially catastrophic bioevent. Project ARGUS is jointly funded by the US Army Medical Research and Materiel Command Telemedicine and Advanced Technology Research Center (USAMRMC-TATRC) and the Department of Homeland Security.

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Fig. 2: Situation Awareness Tool (High-lighting Europe)

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What is the ISIS center at Georgetown University?

📄 PERPLEXITY

The ISIS Center at Georgetown University is not related to the terrorist organization ISIS. Instead, it stands for Imaging Science and Information Systems Center. It is a research center under the Department of Radiology at the Georgetown University Medical Center ¹. The center focuses on the development of advanced medical imaging technologies and information systems ². It was established in the 1980s and 1990s and was led by Seong K. Mun ³. The center is not to be confused with the Center for Security Studies, which is another academic research center in the School of Foreign Service that offers a master's degree program ⁴.

1  idealist

2  georgetown

3  georgetown

4  georgetown

What is the outcome of the lawsuit between Georgetown College and the former employees over Project Argus patent rights

📄 PERPLEXITY

Georgetown College sued two former employees who refused to give up their patent rights to inventions for "Project Argus," a federally funded global pandemic warning system ¹. The outcome of the lawsuit is unclear, as there are no recent reports on the case. However, the lawsuit suggests that Georgetown College claims ownership of the patent rights to Project Argus ¹. It is possible that the case was settled out of court or is still ongoing. There are no further details on the outcome of the lawsuit.

¹ C courthousenews



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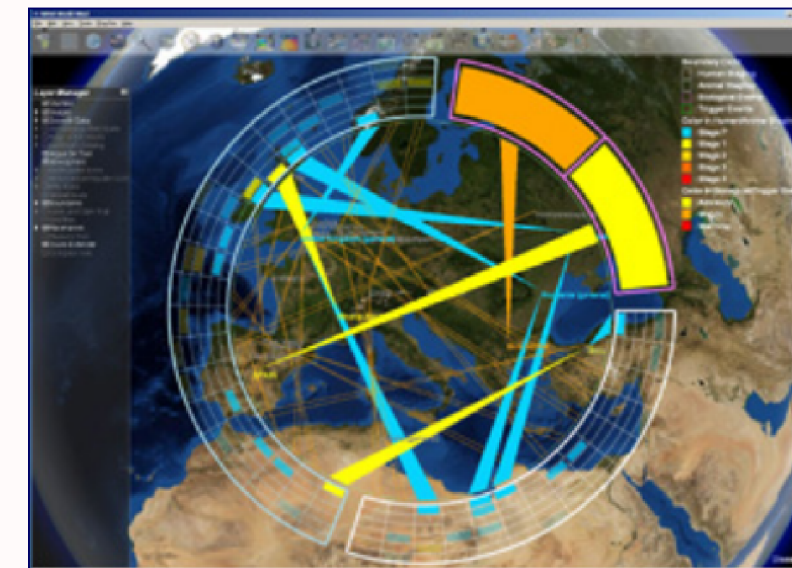


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